

# Non-cigarette tobacco products: what have we learnt and where are we headed?

Richard J O'Connor

## Correspondence to

Professor Richard J O'Connor,  
Associate Professor of  
Oncology, Department of Health  
Behavior, Roswell Park Cancer  
Institute, Elm and Carlton  
Streets, Buffalo, New York  
14263, USA; richard.oconnor@  
roswellpark.org

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## ABSTRACT

A wide variety of non-cigarette forms of tobacco and nicotine exist, and their use varies regionally and globally. Smoked forms of tobacco such as cigars, bidis, kreteks and waterpipes have high popularity and are often perceived erroneously as less hazardous than cigarettes, when in fact their health burden is similar. Smokeless tobacco products vary widely around the world in form and the health hazards they present, with some clearly toxic forms (eg, in South Asia) and some forms with far fewer hazards (eg, in Sweden). Nicotine delivery systems not directly reliant on tobacco are also emerging (eg, electronic nicotine delivery systems). The presence of such products presents challenges and opportunities for public health. Future regulatory actions such as expansion of smoke-free environments, product health warnings and taxation may serve to increase or decrease the use of non-cigarette forms of tobacco. These regulations may also bring about changes in non-cigarette tobacco products themselves that could impact public health by affecting attractiveness and/or toxicity.

## BACKGROUND

Tobacco use is projected to kill 1 billion people during the 21st century. While the majority will likely be killed by their use of cigarettes, tobacco use in other forms also contributes to worldwide morbidity and mortality.<sup>1</sup> Table 1 lists a selection of different classes of non-cigarette forms of tobacco use, including smoked products, smokeless products and also non-tobacco delivery of nicotine.<sup>2</sup> Such products have historically been treated differently from cigarettes for tax and regulatory purposes, and often have longer histories of use than manufactured cigarettes. All forms of tobacco use have negative health consequences, though the severity of those consequences can vary substantially among products.<sup>1</sup> There is evidence that some tobacco and nicotine products may pose less of a health hazard than cigarette smoking and so could potentially play a role in reducing morbidity and mortality due to smoking.<sup>3</sup> However, there is evidence that the public broadly misperceives the relative risks of smoking, tobacco use and nicotine, erroneously thinking smoked tobacco products (eg, waterpipes, cigars, pipes) are less hazardous than cigarettes while believing smokeless forms to be as or more hazardous, and overestimating the health effects due to nicotine.<sup>4–8</sup>

The current paper attempts to describe non-cigarette forms of tobacco as threats to and potential opportunities for public health and tobacco control. This paper is not intended to

thoroughly review all tobacco product characteristics, their health effects, or usage patterns. Rather, it aims to use recent history to inform where opportunities and challenges for tobacco control and public health may arise.

## OVERVIEW OF NON-CIGARETTE TOBACCO PRODUCTS

Use of other forms of tobacco can be divided into three broad categories: other smoked products, smokeless products and nicotine products. Each will be discussed in turn below.

### Smoked tobacco products

Smoked forms of tobacco other than cigarettes include cigars, pipes, kreteks, bidis and waterpipes. Their use is characterised by the burning of tobacco, and the smoke may be inhaled or may be held in the mouth. In some regions, a phenomenon known as 'reverse smoking' is sometimes observed, wherein the lighted end is placed in the mouth.

### Cigars and pipes

Cigars are traditionally comprised of shredded tobacco wrapped in tobacco leaf, though modern mass-produced products often employ reconstituted tobacco sheet in wrappers.<sup>9</sup> Subvarieties of cigar vary by size, from cigarette-like little cigars (which often have a filter) to cigarillos to large cigars (which themselves vary tremendously).<sup>10 11</sup> Cigar smoking enjoyed resurgence in the US in the 1990s, particularly among adolescents and those believing it to be less hazardous than cigarettes.<sup>9 12–16</sup> The use of cigars and wrappers (blunts) to administer marijuana and other drugs also has generated concern.<sup>17–20</sup> Pipes are traditionally composed of a bowl (made of clay or other non-combustible material) where the tobacco is placed for burning, attached to a stem through which the smoke is drawn. The tobaccos used in pipes may sometimes be flavoured. Data on characteristics on cigars and pipes are less commonly available than those for cigarettes.<sup>9 21–25</sup> Rickert and colleagues reported that total particulate matter extracts from cigars and cigarillos were up to 200% more mutagenic, and pipes 44% more mutagenic per unit of nicotine, relative to cigarette smoke.<sup>24</sup> Henningfield *et al* have shown that cigars differ in pH levels, which may affect their delivery of nicotine and therefore their abuse potential.<sup>25</sup> A consistent finding of studies examining smoking behaviours and exposures from pipes and cigars is that former cigarette smokers who adopt cigar or pipe use as a harm reduction strategy typically continue to inhale, whereas primary cigar and pipe users generally do not inhale.<sup>26–31</sup> This is confirmed

**Table 1** Examples of non-cigarette forms of tobacco and nicotine use

Smoked	Smokeless	Non-tobacco
Cigars	Chewing tobacco	Nicotine replacement therapy
Pipes	Moist snuff	Electronic nicotine delivery devices
Bidis	Dry snuff	
Kreteks	Betel quid (with tobacco)	
Waterpipes	Guthka	
Cheroot	Toombak	
	Dissolvable tobacco	

by epidemiological studies, where smokers who have switched to pipes or cigars show little benefit in terms of mortality.<sup>32–33</sup> Cigar and pipe use are associated with cancers of the mouth, nose and upper airway,<sup>32–34–40</sup> while cigar use, but not pipe use, appears to be associated with pancreatic cancer.<sup>41</sup>

### Bidis and kreteks

More regionally specific smoked products are bidis and kreteks. Bidis consist of small amounts of tobacco flake and sometimes other flavourants wrapped in a non-tobacco leaf (tendu or temburni) and bound with string. The majority of Indian bidis are hand rolled in a decentralised cottage industry. Kreteks are cigarette-like products originating in Indonesia where tobacco and clove buds are combined with other flavourings before wrapping in paper. The majority of these are machine manufactured in a manner similar to cigarettes. Bidis are the most commonly smoked product in India (even more so than cigarettes), while kretek smokers are more prevalent than 'white cigarette' smokers in Indonesia.<sup>1–2</sup> However, both products are also used outside their 'native' regions, including Europe and North America. Studies in the US indicate substantial ever use of bidis and kreteks among adolescents and young adults, though it is often coincident with cigarette smoking and use of other tobacco products and perceived to be less hazardous than cigarettes.<sup>42</sup> Particular concern has also been expressed about the role of eugenol in the smoke of kreteks, which may act as an anaesthetic in the airways, reducing harshness and making smoke more palatable, particularly to young people.<sup>43–45</sup> Smoking machine studies find bidis and kreteks to yield high amounts of toxicants.<sup>46–50</sup> Studies examining smoking behaviours and exposures with bidis and kreteks have shown them to differ little from manufactured cigarettes in terms of smoking patterns, CO exposure and nicotine delivery.<sup>51–53</sup> In terms of disease risks, bidi use is strongly associated with mortality,<sup>54</sup> particularly lung and oral cancers,<sup>55–59</sup> and tuberculosis.<sup>59–60</sup> Kretek smoking also shows significant mortality risks, though data are less widely available.<sup>61–62</sup>

### Waterpipes

Another smoked form of tobacco use is waterpipe, known in various regions by names such as shisha, hookah and narghile.<sup>63</sup> Waterpipes typically employ indirect heating of tobacco (often via charcoal), where smoke generated is passed through a chamber containing water before reaching the user via a hose.<sup>63</sup> Beginning in the 1990s, waterpipes re-emerged as a popular way to use tobacco.<sup>64–67</sup> A driver in the growth of waterpipe use may have been the introduction of flavoured maasal tobacco preparations for use in waterpipes and the proliferation of waterpipe cafes.<sup>67</sup> Waterpipe use appears to have become especially popular among university students,<sup>68–72</sup> many of whom believe that it is less hazardous than cigarette smoking.<sup>73–76</sup> Studies of use behaviours indicate intake of smoke orders of magnitude higher

than from cigarettes with equivalent nicotine exposure.<sup>77–82</sup> A clear product design and performance issue is the use of charcoal as a heating source, which generates copious amounts of carbon monoxide and polycyclic aromatic hydrocarbons.<sup>63–83–84</sup> The literature on the health effects of waterpipe use is less robust than that for cigarettes or smokeless tobacco,<sup>63</sup> but indicates that waterpipe use is associated with cancer, heart disease, lung function, infectious diseases and reproductive effects.<sup>85–87</sup>

### Smokeless tobacco

Smokeless tobacco is a broad term encompassing a number of different types of tobacco products used orally or nasally. Among these are chewing tobaccos, dry snuff, moist snuff, Swedish-style snus, betel quid, guthka, zarda, toombak and newer dissolvable tobacco products.<sup>88</sup> A number of other papers have examined the variety of products and their contents.<sup>89–94</sup> Because the blanket term 'smokeless tobacco' covers such a wide gamut of products, explaining epidemiological associations between ST use and health becomes complicated. Smokeless tobacco as used in Sweden may be linked to pancreatic cancer<sup>95–96</sup> and cardiovascular disease,<sup>97–98</sup> but does not appear to be associated with other cancers.<sup>95–99–100</sup> In North America, use of chewing tobacco and moist snuff is associated with oral cancer, as well as cancers at other sites, and cardiovascular disease.<sup>88–100</sup> For smokeless products as used in South Asia, there is substantial and consistent evidence for oral cancer and other health effects.<sup>88–101–102</sup> There is also evidence that forms of ST have adverse effects in pregnancy, including preterm delivery.<sup>85</sup> Many of the observed differences in disease effects may be due to the composition of the products.<sup>103</sup> Stanfill and colleagues examined variation in smokeless products worldwide, finding that tobacco-specific nitrosamine levels varied by several orders of magnitude (ranging from 4.5 to 516 000 ng/g).<sup>89</sup> Even within the US moist snuff market, data show variations in tobacco-specific nitrosamine content up to 18-fold among leading products.<sup>90</sup> Another knotty terminological issue is the adoption of the Swedish word 'snus' by multinational tobacco manufacturers (eg, Philip Morris, RJ Reynolds, British American Tobacco (BAT)) to describe their newer smokeless products; some of the newer products called 'snus' do not share key characteristics with the snus sold in Sweden, such as nicotine delivery.<sup>104</sup>

### ST and harm reduction

Beginning in the 2000s, data from Sweden emerged suggesting the use of snus may have contributed to declines in cancer and smoking rates.<sup>105–109</sup> However, this interpretation remains controversial as it is unclear the extent to which circumstances in Sweden would generalise to other markets, such as Europe or Australia, where sale of smokeless tobacco is currently banned or to the US where smokeless containing more toxins has long been available.<sup>110–113</sup> Nonetheless, these data have formed the basis for movements to promote snus-type products (herein referred to as low nitrosamine smokeless tobacco (LNST)) more broadly as alternatives to cigarettes for smokers.<sup>114–115</sup> The suggestion that smokers be encouraged to move towards another tobacco product has prompted heated debate within the tobacco control community.<sup>116–122</sup>

There is general agreement in the scientific community that the health hazards from LNST are lower than those of cigarette smoking on the individual level of analysis.<sup>112</sup> The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) notes in its report: 'It is undeniable that for an individual substitution of tobacco smoking by the use of moist snuff would decrease the incidence of tobacco related

diseases'.<sup>112</sup> The major source of argument is in projecting the larger public health effects of such promotion; these arguments grow primarily from different approaches to public health ethics.<sup>123</sup> Two primary concerns emerge about the promotion of LNST for harm reduction in current smokers: (1) encouragement of novices (particularly youth) to adopt ST use (including the more toxic forms) and; (2) dual use of cigarettes and ST.<sup>116 121 124</sup> A commonly expressed concern is that youth may be attracted to smokeless products, but eventually move to cigarette use (ie, ST acts as a 'gateway' to smoking). Evidence for this is mixed: Swedish data generally show low levels of ST-to-cigarette transition,<sup>125–127</sup> while North American evidence is equivocal, with some studies showing gateway effects,<sup>128–130</sup> while others do not.<sup>131–134</sup> Observed gateway effects may themselves be explainable in part by underlying factors predicting use of both types of tobacco.<sup>131 133</sup> A second concern has been dual use, or contemporaneous use of ST and cigarettes, which could sustain nicotine addiction, delay cessation and contribute to compensatory smoking of the remaining cigarettes smoked.<sup>124</sup> A related concern is that if smokers turn to ST when they are unable to smoke, the effect of smoking bans on encouraging smoking cessation may diminish.<sup>124 135 136</sup> Data on current patterns of multiple product use are sparse, but indicate that dual users tend to have higher nicotine dependence, though it is unclear whether this is an antecedent or consequence of dual use.<sup>135 136</sup> Also of interest is that increases in dual use were not seen with implementation of worksite smoking restrictions in the US, despite marketing by ST manufacturers.<sup>137 138</sup>

### ST promotion and population health impact

With respect to population impact, there is some concern about attracting new users with reduced risk products into the overall pool of tobacco users, whose acquired disease risk would then offset the reduced disease burden among smokers. Kozlowski and colleagues have made the conceptual point that for a product with substantial risk reduction relative to cigarettes (say, >80%), the amount of uptake would have to be extraordinarily high to offset the benefit of moving smokers away from cigarettes.<sup>139</sup> Levy and colleagues, gaining consensus from leading experts, estimated that LNST was 90% less hazardous than smoking,<sup>140</sup> and that promoting ST could reduce smoking prevalence by 1–3 percentage points, with a small increase in overall ST use.<sup>141</sup> Other attempts to more comprehensively model population effects have come to diverging conclusions.<sup>142 143</sup> Gartner and colleagues modelled loss in health-adjusted life expectancy for four groups relative to never smokers: continuing smokers, smokers who switch to Swedish snus, smokers who quit and snus users who never smoked.<sup>142</sup> Life tables based on the Australian population were used, and potential health outcomes associated with smoking were based on the American Cancer Society's Cancer Prevention Study II (CPS-II) and the Australian Burden of Disease Study, while those associated with snus were based on Levy *et al*,<sup>140</sup> with modelling estimates derived using Monte Carlo simulation. They found little difference in life expectancy loss between those who quit tobacco altogether and smokers who switched to snus, with both far lower than continued smoking. They also noted that 14–25 former smokers would have to adopt snus use to offset the health gain of each smoker who switched to snus, and 14–25 never smokers would have to adopt snus to offset the health benefit of each person who initiated snus rather than smoking.<sup>142</sup> Both of these indicated net public health benefit of snus. Meija and colleagues built their model beginning with non-users and postulating different pathways for initiation and use of cigarettes and smokeless

tobacco: never users, initiated ST and initiated cigarettes (these were further subdivided into stable, health concerned, smoke-free environments and price sensitive smokers).<sup>143</sup> The authors relied on the Levy *et al* expert estimate of 90% risk reduction for ST relative to cigarettes,<sup>140</sup> creating a health effects scale ranging from never smoking (set to 0) to exclusive ST use (mean 11) to exclusive smoking (set to 100). Four scenarios for promotion of ST were considered, which were modelled to influence initiation rates, and Monte Carlo simulation used to model a decision tree leading to overall distributions of health effects. They found little evidence that even aggressive promotion of ST would benefit public health in terms of a downward shift in health effects distribution; indeed the ratios of health effects (compared to the base case) ranged from 0.92 to 1.26, indicating little reduction to slight increase in overall population health impact.<sup>143</sup> These two modelling exercises demonstrate the complexity in trying to assess the downstream impacts of patterns of individual behaviour on population health.

### Non-tobacco nicotine delivery

Of course, use of tobacco products is not the only way humans can self-administer nicotine. Around the world, nicotine-containing medications have been approved in several forms: transdermal patches, gum, lozenges, sublingual tablets, inhalers and nasal sprays. (The nicotine in such medications is ultimately derived from tobacco, rather than synthesised in the laboratory.) All of these products have undergone numerous randomised controlled trials and have demonstrated safety and efficacy in increasing the likelihood of cessation.<sup>144</sup> In most countries, nicotine replacement therapies (NRTs) are approved for brief use (12 weeks) for cessation of smoking, though the UK has recently expanded its indications to assist smokers in reducing their cigarette consumption.<sup>145</sup> The WHO in 2009 added NRT (patches and gum) to its Essential Medicines list, a testament to its safety and efficacy track record and in recognition of the public health need for efficacious smoking cessation treatments in the context of the Framework Convention on Tobacco Control (FCTC).<sup>146</sup> A number of authors have made the case for NRTs as harm reduction products for smokers unable or unwilling to quit.<sup>139 147–150</sup> There is emerging evidence that a substantial minority of NRT use is for reasons other than cessation<sup>151 152</sup> with little evidence of abuse by non-tobacco users.<sup>153 154</sup>

A broad class of products has also emerged over the last two decades that claim to provide nicotine apart from traditional tobacco or pharmaceutical sources. In the 2000s, for example, several websites began offering nicotine lollipops and lip balms, which were rejected by US regulators as unapproved drugs and abuses of the compounding privilege afforded to pharmacists.<sup>155–157</sup> A related product concept marketed several times in different forms is bottled water containing nicotine.<sup>157</sup> Other products have included 'tobacco gel' substitutes for cigarettes, made from tobacco extracts and delivering nicotine transdermally. However, these 'underground' products have tended not to attract much market share.

### Electronic nicotine delivery systems (ENDS)

Electronic nicotine delivery systems (ENDS), however, upset this trend. Emerging in 2006 in China, they became more widely available throughout the world in 2008–2009.<sup>158–160</sup> These devices, often constructed to resemble cigarettes, work by vapourising a solution containing nicotine dissolved with flavourants in a carrier medium (usually propylene glycol).<sup>161</sup> The products have typically been promoted as having reduced

health risk compared to tobacco use and able to be used in situations where smoking is prohibited. The product occupies an interesting place with respect to harm reduction; unlike the case of medicinal nicotine products or even Swedish snus, where data on relative harms are plentiful, data on ENDS are lacking.<sup>161</sup> On the one hand, nicotine delivered by vapour with few known toxicants should theoretically carry relatively low risks, particularly when compared to cigarettes.<sup>162</sup> The limited data available suggest that the products are not likely to approach the health hazards of cigarettes.<sup>161 162</sup> However, on the other hand, significant concerns exist with the purity of ingredients employed, device functionality and quality control, the ease with which devices can be modified by users, and the general lack of oversight in manufacturing or marketing.<sup>163 164</sup> Additionally, the nicotine deliveries of ENDS tested thus far have been significantly lower than that of cigarettes, raising questions of whether they can substitute effectively over the long term.<sup>165 166</sup> Survey studies with self-selected users indicate that ENDS users have used them to quit smoking cigarettes, but thus far no randomised controlled trials have been published.<sup>161 167 168</sup> ENDS availability and promotion has prompted vociferous debate within the tobacco control community of a level commensurate with that surrounding LNST.<sup>160 169</sup>

### WHAT IS COMING OVER THE NEXT 20 YEARS

Predicting the future is always difficult. Still, current trends can sometime be instructive in informing where tobacco control might move in the coming decades. Clearly in the last 20 years, the rise of a tobacco control movement with strong moral force coupled to strong science has been instrumental in driving numerous policy changes, such as indoor smoking restriction (predicated on the rights of non-smokers to breathe unpolluted air), advertising bans (reducing the exposure of children to smoking promotion), taxation (providing an economic disincentive for smokers to continue) and education (providing health warnings to smokers and non-smokers alike). Circumstances in the future may provide opportunities for tobacco control to exert these influences on the use of non-cigarette tobacco products in ways that benefit public health.

#### Impacts of regulatory policy

##### Framework convention on tobacco control

The FCTC, while ostensibly aiming to reduce the health effects of all forms of tobacco use through policy intervention, has largely focused on the effects and regulation of cigarette smoking. That is, there has been relatively less attention paid to policies that may impact the use of other forms of tobacco. This is especially problematic in markets where manufactured cigarettes do not dominate, such as India. The mere fact of the FCTC and its early focus on cigarette-relevant policies may play a role in shaping the future of non-cigarette tobacco products in the marketplace.

##### Smoke-free environments

The implementation guidelines for Article 8 recommend 100% bans in worksites, restaurants and bars. Movements are now in place to restrict smoking in certain public outdoor spaces as well (eg, parks, beaches, building entryways). This may create market pressures on smokers still addicted to nicotine to seek out alternative delivery systems. Indeed, marketing by tobacco companies targeting new smokeless products towards smokers in the US have taken this approach.<sup>170–172</sup> Whether these

strategies will be expanded to other markets is presently unclear, as the EU and Australia show little sign of lifting their restrictions on snus sales. In addition, some smoking restriction regulations have included exemptions for waterpipe cafes, which may add to their appeal, inasmuch as they can be used indoors and in social situations.<sup>173 174</sup> The extent to which these current loopholes are closed may do a lot to curtail growing interest in alternative smoked products.

#### Health warning labels

The wider adoption of effective pictorial health warnings that depict the hazards of tobacco use (Article 11) will play a crucial role in educating tobacco users, particularly in developing countries. Evidence consistently shows that pictorial health warnings have contributed to increased knowledge of specific health effects of smoking in a number of countries.<sup>175–177</sup> Health warnings clearly can and should be appropriately and accurately applied to all tobacco products. However, one recent study showed that graphic health warnings on smokeless tobacco products overwhelmed acceptance of a scientifically valid relative health risk message on the packaging and actually increased false beliefs about the relative health effects of ST and cigarettes.<sup>178</sup> This raises practical considerations for communicating relative risks of products to the public. If one considers pictorial health warnings as a broad system for health education, then one could imagine coordinated warnings across products distinguishing the most from least hazardous by virtue of the health effects displayed (in markets where appropriate). This could serve to simultaneously discourage initiation, encourage cessation, and also make apparent the relative risks of different products. Such an approach could correct the prevalent misperceptions that cigars, waterpipes and other smoked products are less hazardous than cigarettes and also the misperception that LNST is equally or more hazardous, while not explicitly promoting any particular product class.

#### Product regulation

Articles 9 and 10 of the FCTC deal most directly with the regulation and disclosure to governments and the public of tobacco product contents and emissions. At the 2010 conference of parties, partial guidelines for these related articles were released. The parties noted that the regulation of tobacco products could help to reduce morbidity and mortality '... by reducing the attractiveness of tobacco products, reducing their addictiveness... or reducing their overall toxicity'.<sup>179</sup> The specific recommendations relevant to non-cigarette tobacco products are summarised in table 2. The FCTC envisions broad authority for agencies to begin to constrain the production of tobacco products in various ways. This may mean greater authority in countries such as India, for example, to reduce the variety of smokeless tobacco products by restricting non-tobacco additives (eg, areca nut, herbs and spices). Opportunities exist to obtain more information about tobacco products and to regulate their contents and emissions. Such actions could set an achievable bar for non-cigarette products elsewhere in the world. The Swedish experience shows that oral tobacco products could be made to contain far fewer toxicants than are currently seen in South Asian products and even most North American smokeless products, yet achieve popularity in the market.<sup>89</sup> The WHO Study Group on Tobacco Product Regulation (TobReg), in a technical report, has laid out reasoning for limits on specific toxicants in smokeless tobacco products, such as nitrosamines and heavy metals, which are technically achievable.<sup>180 181</sup> Ayo-Yusuf and Connolly point to toxicological principles that could

**Table 2** Selected recommendations regarding regulation and disclosure of tobacco product characteristics and emissions, 4th Conference of the Parties to the Framework Convention on Tobacco Control (FCTC), 2010

Characteristic	Recommendations
Laboratory standards	For purposes of disclosure, testing laboratories should meet standards for ISO 17025 accreditation Compliance laboratories should be independent of the tobacco industry
Financing	Consider various means to pay for product regulatory systems, including dedicated taxes, licensing fees, product registration fees and non-compliance levies
Confidentiality	Apply appropriate legal frameworks to prevent unauthorised use and disclosure of information claimed to be commercially sensitive or confidential
Content reporting	Require manufacturers to disclose actual quantities of ingredients used in manufacture of products by product type and brand style in a standardised format Require manufacturers to disclose the suppliers, types and characteristics of tobacco leaf by product type and brand style (eg, variety of tobacco, reconstituted sheet and/or expanded tobacco use) Require manufacturers to notify authorities of changes to products Require manufacturers to provide a statement of purpose underlying the use of ingredients
Content regulation	Regulate or restrict ingredients that may be used to increase palatability of tobacco products (eg, cinnamon, mint), create impression of health benefits (eg, vitamins), or are associated with energy or vitality (eg, caffeine)
Compliance and enforcement	Impose legal responsibilities on manufacturers for compliance and impose penalties for violations Consider sampling products from facilities and retailer outlets for compliance testing Specify appropriate sanctions for non-compliance and ensure authorities have power to seize and destroy non-compliant product and levy penalties

help shape the regulation of existing and new ST products, noting that nitrosamines and cadmium were associated with the largest estimated cancer risks.<sup>182</sup> Thus, the next 20 years could witness the emergence of performance standards for smokeless tobacco products.

The prospects for product-level regulatory action regarding products such as cigars, bidis, kreteks and waterpipe are less clear. Data on the characteristics of other tobacco products besides cigarettes and smokeless tobacco are sparse, and so additional research may be necessary to identify key compounds of health concern before product standards or other product-level regulations could be promulgated. However, decentralised production and cottage industries such as bidi making may prove a complication in enforcing product standards. Still, the flavoured tobaccos used in waterpipes (maasal) could be targeted by regulators under the recommended guidelines for Articles 9 and 10 dealing with the use of flavourings to increase the attractiveness of tobacco products. Given this appears to have been key to the growth in their popularity,<sup>64 67</sup> limiting or eliminating the use of flavourants may lead to a decline in waterpipe use.

### US Food and Drug Administration (FDA)

While the US has not ratified FCTC, the regulatory authority provided to the US FDA in 2009 provides a mechanism to achieve some of the same ends and may help to create precedents for other countries to follow with respect to product regulation under Articles 9 and 10. The FDA has banned flavoured cigarette products (other than menthol), restricted the

use of misleading terms such as 'light' and 'mild', created a registration and reporting system for manufacturers, and instituted retail sales inspections and enforcement. The law also gives the FDA broader powers to shape the tobacco product market for the protection of public health, such as issuance of product standards, requirements for premarket approval for new products, and formal determination of substantial equivalence for product modifications. Since it has only had jurisdiction over tobacco for 2 years, the agency is still defining the boundaries of its authority. The FDA regulations have thus far not been applied to cigars, so while kreteks were nominally banned in the US under FDA legislation (as clove was not a permitted characterising flavour), some have been reintroduced as little cigars.<sup>183</sup> A court decision (*Sottera vs FDA*) essentially declared ENDS to be tobacco products rather than drugs or medical devices (inasmuch as they are 'made or derived from tobacco' and not making a therapeutic claim), a classification to which the agency acceded. Around the same time, the FDA declared two products (*Ariva BDL* and *Stonewall BDL*), which had been submitted for consideration as modified risk tobacco products, to be not tobacco products, a decision apparently driven by undisclosed details in the manufacturing process.<sup>184</sup> The agency is pursuing rulemaking to bring all products made or derived from tobacco under the same set of premarket and postmarket rules governing cigarettes and smokeless tobacco.<sup>185 186</sup>

The most important opportunities for the FDA to shape tobacco control into the future may be in the setting of performance standards; the premarket process for new or substantially equivalent products; and, separately premarket authorisation of modified exposure/risk claims. Product standards for smokeless tobacco, for example, could restrict the manipulation of pH and mandate lower concentrations of toxicants (eg, heavy metals, nitrosamines). Clearly, this would be technically achievable; as Hecht and coworkers have pointed out, the technology exists for US smokeless manufacturers to make less toxic products, yet they have not thus far applied it.<sup>181</sup> Clamoured for by health groups for decades following on the public health disaster of low-tar cigarettes, the FDA will have the opportunity to formally evaluate many tobacco products before they are sold. Required evaluations of substantially equivalent products mean that companies must demonstrate that modifications to their products (relative to a reference product) do not raise health concerns, meaning that product changes would have to be justified on a public health basis, rather than simply on toxicology. Claims for risk or exposure reductions for non-cigarette products as compared to cigarettes would have to be scientifically justified, including evidence that consumers would not be misled by the marketing and that there would be a net public health benefit. It is likely that manufacturers will pursue such claims for LNST and possibly dissolvable tobacco and ENDS. Whether and how many such claims are permitted will depend on how the agency sets the evidentiary standard. The Tobacco Products Scientific Advisory Committee (TPSAC) is currently charged with producing a report on the public health effects of dissolvable tobacco products (eg, *Ariva*), and a committee of the Institute of Medicine is considering scientific standards for studies of modified risk tobacco products, so this is an active and evolving area. It is clear, however, that providing a firm evidence base to guide regulatory decision making will become increasingly important.

### Taxation

Tax policies also have potential for shaping the development of the tobacco market. Taxation has effectively been used around

the world as a means to reduce cigarette consumption; in general, a 10% increase in price brings about a 1% decrease in smoking prevalence. However, this effect can be influenced by affordability of the product; that is, its 'real price' in the context of income growth and inflation.<sup>187</sup> Two types of taxes can be applied: specific (a fixed amount per some unit) or ad valorem (proportional to value). In general, specific taxes are more advantageous than ad valorem taxes to companies making premium-priced brands,<sup>187</sup> since they tend to enhance price differentials.

Taxes can vary significantly for non-cigarette tobacco products. Cigar and pipe tobacco taxes are typically based on weight, and vary from jurisdiction to jurisdiction. In the US, smokeless tobacco is subject to specific and ad valorem taxes; at the federal level, a specific (weight-based) tax is used, while in most states an ad valorem tax is applied.<sup>188</sup> Rates vary widely from 100% of wholesale price in Wisconsin to no tax at all in Pennsylvania. In India, cigarettes are taxed at rate over 60 times higher than that for bidis, while throughout the Middle East waterpipe tobacco is taxed at ad valorem rates ranging from 2% in Libya to 108% in Lebanon.<sup>187</sup> Clearly, then, there is wide variability in the tax treatment of non-cigarette tobacco products. Thus far, in markets where they are permitted, ENDS have not been subject to tobacco taxes.

Loopholes and complexities in tobacco tax structures, as well as crossborder differences in price, create incentives for tax avoidance.<sup>187</sup> Consumers with the means to do so will tend to seek out cheaper products or cheaper sources of product, such as using discount brands, switching to other tobacco products, or travelling to locations where prices/taxes are lower.<sup>189</sup> Manufacturers can also alter or reposition their products to take advantage of tax loopholes. Little cigars emerged partially in response to the tax differential between cigarettes and cigars at the state and federal level.<sup>11</sup> Following a 2009 Federal excise tax increase in the US that largely equalised taxes between cigarettes and little cigars, some manufacturers added weight to their 'little cigars' so that they would qualify as less-taxed 'large cigars'.<sup>190</sup> And, other manufacturers reclassified their rolling tobacco as 'pipe tobacco' for similar tax reasons, resulting in a sudden increase in pipe tobacco sales.<sup>191</sup>

Consumers, when faced with price differentials, may substitute a related product for the desired one, for example, discount and roll-your-own (RYO) cigarettes for premium ones.<sup>189</sup> This can also extend to non-cigarette tobacco products, though the economics for these products are not as well studied. A key question in this context is the cross-price elasticity, or the change in consumption of the substitute that occurs with an increase in the price of cigarettes.<sup>187</sup> If this is positive, then the products are substitutes, while if it is negative, the products are complements. Some have suggested taking advantage of this substitution behaviour by setting tax structures to incentivise smokers to adopt less hazardous forms of tobacco/nicotine use.<sup>115 147</sup> Others argue that all tobacco products should be taxed consistently (eg, a comparable share of price) so as to reduce potential for substitution as a method of tax avoidance, discourage initiation and encourage cessation of all products.<sup>188 192</sup> Which is the preferable approach may depend on the specifics of the available products and regulatory conditions. In the US, where the FDA can formally evaluate modified risk/exposure claims, there may be opportunities to provide tax advantages to products that are authorised to make such claims as a way to draw users away from more hazardous products (eg, tax exempt or low tax relative to other products).

### Could non-cigarette tobacco or nicotine products attract new markets?

The dominance of the cigarette may be wavering in certain markets, even as cigarette manufacturers enter new markets. Clearly, waterpipes are growing in popularity worldwide, fed by attractive flavours, imagery and perceptions of safety.<sup>67</sup> BAT, Swedish Match, RJ Reynolds and Philip Morris believe at least some smokers may be attracted to smokeless tobacco.<sup>172 193</sup> They have acquired smokeless tobacco manufacturers and/or introduced smokeless tobacco products, often linked to established cigarette brand names. Historical context also suggests that populations can shift with regard to their preferred delivery systems for nicotine.<sup>194 195</sup> Use of chewing and snuffing tobacco products was impacted by anti-spitting laws enacted in the late 1800s and early 1900s to combat the spread of tuberculosis and other infectious diseases.<sup>194</sup> Smoked products then became acceptable substitutes. A century later, the pendulum appears to be swinging in the opposite direction, particularly as the health hazards of passive smoking were established. Cigarette smoking is becoming a stigmatised behaviour as prevalence declines and restrictions proliferate.<sup>196–199</sup> Since smokeless tobacco use, particularly in its spitless forms, is less visible to others, it may carry less social stigma than does smoking. Medicinal nicotine and ENDS may have similar advantages vis a vis social acceptability. So, social pressures being applied to cigarette use could contribute to making non-cigarette tobacco relatively more attractive to those addicted to nicotine. And as noted earlier, increasing cigarette taxes (and therefore prices) may make substitution of less taxed tobacco products evermore economically attractive so long as product differentials in tax treatment persist.

An interesting case study to watch is how ENDS have achieved notoriety. ENDS have spread via the internet<sup>159 160</sup> and pressure groups and trade associations created to promote them.<sup>200</sup> A community of users ('vapers') has emerged, facilitated by the internet and social networking, arguing forcefully for light regulation, if any, for the product (eg, Consumer Advocates for Smoke-free Alternatives Association). Message boards (eg, Vapor Talk Forum) allow users to exchange experiences, as well as to obtain information about modifying ENDS and sharing 'how to' instructions. The ease of peer-to-peer communication facilitated by the internet may allow novel product use to diffuse more widely than by traditional channels.<sup>201</sup> Peer-to-peer communication can be an effective form of persuasion. If one considers a 'diffusion of innovations' framework, this makes perfect sense; early adopters are often highly influential in driving new product use and popularising niche products.<sup>202</sup> The ENDS issue may reflect broader trends in social networking and the promotion of tobacco products. Internal documents indicate that R.J. Reynolds explored viral strategies to market its Eclipse reduced risk cigarette,<sup>203</sup> and there is evidence that tobacco companies have been directly and indirectly marketing via social media.<sup>204–206</sup> Message boards for Camel Snus showed that participants advised one another on product use, purchase locations and suggestions on improving the product.<sup>206</sup> These developments may have implications for how research findings and regulatory actions regarding tobacco products are communicated and understood in the 21st century. That is, scientists and public health advocates may increasingly have to rely on alternative strategies to disseminate information into the public sphere, complementing the traditional outlets of journal publications and government reports.<sup>207</sup> Translating knowledge to regulators and the public, who will increasingly

### What is already known on this topic

All forms of tobacco use have negative health consequences, though the severity of those consequences can vary substantially among products.

### What this paper adds

Over the next 20 years, increased regulation and social disapproval of cigarette smoking may increase the attractiveness of non cigarette tobacco and nicotine products. This represents both a challenge and opportunity for public health and tobacco control.

communicate among themselves, may require much more direct and 'real-time' engagement by tobacco control scientists.

### CONCLUSIONS AND RESEARCH AGENDA

A wide variety of non-cigarette forms of tobacco and nicotine exist, ranging from smoked forms to smokeless forms to tobacco-free nicotine. Non-cigarette forms of tobacco are widely available, and their use varies regionally and globally. Smoked forms of tobacco such as bidis, kreteks and waterpipes have high popularity and are often perceived erroneously as less hazardous than cigarettes, when in fact their health burden is similar. Smokeless tobacco products vary widely around the world in form and associated health hazards, with some clearly toxic forms (eg, in South Asia), and some forms with far fewer hazards (eg, in Sweden). A market is also burgeoning for nicotine delivery systems not directly reliant on tobacco (eg, ENDS). Broadly, while there is a continuum of risk for tobacco products, public perceptions and indeed regulatory schemes do not often coincide with actual risk.<sup>1–3</sup> Regulations under the FCTC and the US FDA may occasion a shift away from cigarettes towards other forms of tobacco use, and these regulations may also bring about changes in non-cigarette tobacco products themselves that could impact public health by reducing attractiveness and/or toxicity.

Research needs in tobacco control may shift if non-cigarette tobacco products grow in popularity around the world. It will be important to make sure that independent science is available to guide governments in making evidence based decisions, as it has for the past 20 years of tobacco control activity. Below is a list of priority areas where greater research effort could be directed:

- ▶ More thorough characterisation of non-cigarette tobacco products in terms of composition and toxicity to inform regulators developing reporting guidelines.
- ▶ Modelling contributions of non-cigarette tobacco product use to overall morbidity and mortality, in particular modelling replacement of cigarette smoking by other forms of tobacco/nicotine use.
- ▶ Development of appropriate health warning messages and pictorials for non-cigarette tobacco products.
- ▶ Effects of product standards for various smokeless tobacco products on individual and population health.
- ▶ Effects of policy interventions that discourage cigarette use on the use of other tobacco products.

- ▶ Impacts of social media and social networks on the diffusion of non-cigarette tobacco use.

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