

The WHO's Opposition to Tobacco Harm Reduction:

A Threat to Public Health?

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Introduction

This brief seeks to assess and critique the lack of transparency, openness and accountability of the World Health Organization's Framework Convention on Tobacco Control (FCTC). It considers the results, including arbitrary, ideologically driven recommendations, which in turn lead to domestic regulations that are unduly restrictive—and in some cases counterproductive.

The brief begins with a description of the FCTC's objective and an assessment of the extent to which it has achieved that objective. It then considers the reasons tobacco consumption has fallen in some countries, including access to information, prices and use of harm reduction products. It contrasts these successes with the policies promoted by the FCTC, which have largely focused on "demand reduction" to the exclusion of harm reduction.

The brief elucidates the reasons for the WHO's and its FCTC's hostility to tobacco harm reduction and adumbrates its consequences. It contrasts this opposition to less harmful nicotine-containing products with the WHO's support for harm reduction in other contexts, and questions the legitimacy of this approach in light of the WHO's commitment to enable people to improve their own health, and more generally to human rights. It then evaluates the governance structure of the FCTC, comparing it to the governance ideal supported by other UN bodies.

The brief concludes with some suggestions as to how the FCTC might align its governance with the WHO's commitments and objectives.

Is the FCTC Meeting Its Objective?

In 2004, the World Health Organization (WHO) estimated that smoking was responsible for 12% of all deaths globally. Such concerns motivated the establishment, by the WHO, of a Framework Convention on Tobacco Control (FCTC). The process of establishing the FCTC began with a resolution of the World Health Assembly in 1999. Ratified in 2004, the FCTC came into force in 2005. Its objective is given in Article 3:

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

So, how successful has the FCTC been in achieving its objective? Smoking prevalence globally has declined since 2005, as shown in Figure 1.⁴ However, the rate of decline appears to have fallen: as Figure 2 shows, the rate of decline in smoking prevalence was greater for all regions during the period 1996 to 2006 than during the period 1980 to 1996, but since then it has fallen. Worse, in China, home to the world's largest number of smokers, smoking prevalence increased annually by about 0.2% between 2006 and 2012.

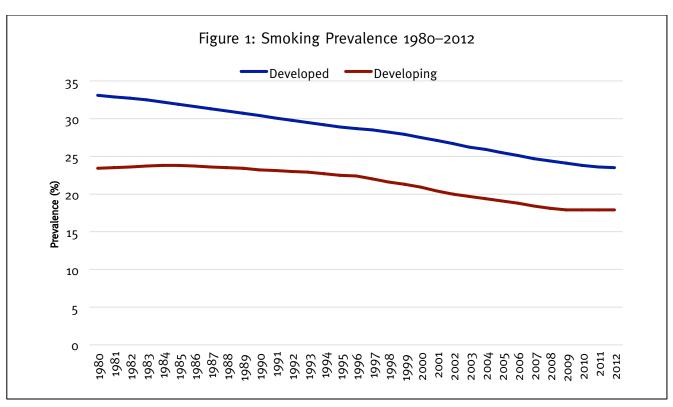
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WHO Global Report: Mortality Attributable to Tobacco, (Geneva: World Health Organization, 2004). Available at: http://whqlibdoc.who.int/publications/2012/9789241564434_eng.pdf, accessed 2/27/2014.

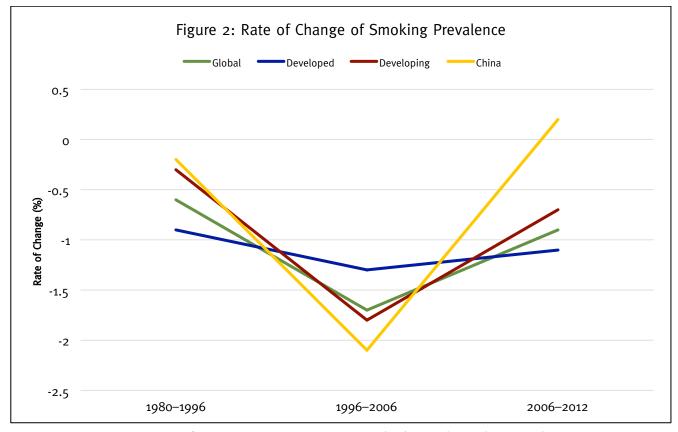
WHO Framework Convention on Tobacco Control, (Geneva: World Health Organization, 2003). Available at: http://whqlibdoc.who.int/publications/2003/9241591013.pdf, accessed 9/6/2016.

World Health Assembly, WHA Resolution 52.18—Towards a WHO framework convention on tobacco control, 1999. Available at: http://www.who.int/tobacco/framework/wha_eb/wha52_18/en/, accessed 9/6/2016.

In most countries, national data on smoking are collected only sporadically, making it difficult to draw firm conclusions regarding either prevalence or total consumption. Figure 1 in based on estimates using surveys and models prepared by a team led by Dr. Marie Ng of the Institute for Health Metrics and Evaluation, University of Washington, Seattle. See: Marie Ng, Michael K. Freeman, Thomas D. Fleming, Margaret Robinson, Laura Dwyer-Lindgren, Blake Thomson, Alexandra Wollum, Ella Sanman, Sarah Wulf, Alan D. Lopez, Christopher J. L. Murray, MD, and Emmanuela Gakidou, "Smoking Prevalence and Cigarette Consumption in 187 Countries, 1980–2012," *Journal of the American Medical Association*, 2014, Vol.311(2), pp. 183-192. doi:10.1001/jama.2013.284692. See also World Health Organization, *WHO global report on trends in prevalence of tobacco smoking 2015*, (Geneva: World Health Organization, 2015).



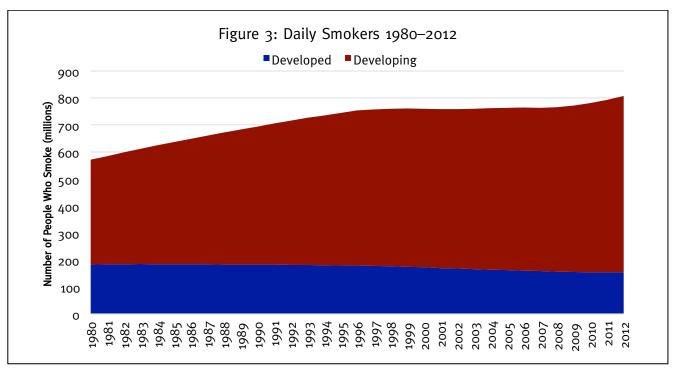
Source: Data from M. Ng, M.K. Freeman, T.D. Fleming, et al., *Smoking prevalence* and cigarette consumption in 187 countries, 1980–2012. JAMA, 2014.



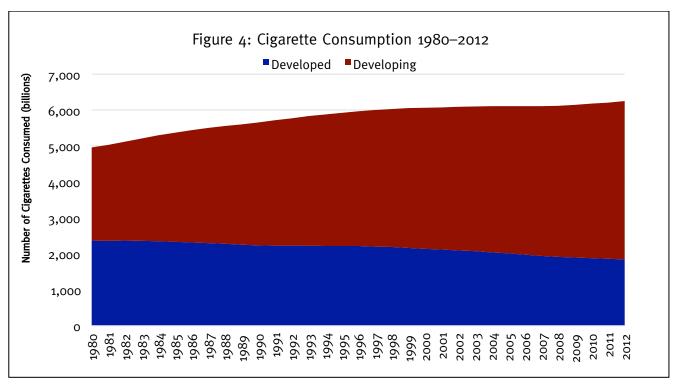
Source: Data from: M. Ng, M.K. Freeman, T.D. Fleming, et al., *Smoking prevalence* and cigarette consumption in 187 countries, 1980–2012. JAMA, 2014.

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Meanwhile, between 2005 and 2012 the total number of smokers globally continued to increase—as shown in Figure 3. And, as Figure 4 shows, sales of cigarettes also increased.



Source: Data from: M. Ng, M.K. Freeman, T.D. Fleming, et al., *Smoking prevalence* and cigarette consumption in 187 countries, 1980–2012. JAMA, 2014.



Source: Data from: Ng M, Freeman MK, Fleming TD, et al., *Smoking prevalence and cigarette consumption in 187 countries, 1980–2012.* JAMA, 2014.

An analysis of WHO indicators published by *The Lancet* in 2015 concluded:

During the most recent decade (2000–10), the prevalence of tobacco smoking in men fell in 125 (72%) countries, and in women fell in 155 (87%) countries. If these trends continue, only 37 (21%) countries are on track to achieve their targets for men and 88 (49%) are on track for women, and there would be an estimated 1.1 billion current tobacco smokers (95% credible interval 700 million to 1.6 billion) in 2025. Rapid increases are predicted in Africa for men and in the eastern Mediterranean for both men and women, suggesting the need for enhanced measures for tobacco control in these regions.⁵

Since Africa, the Middle East and Asia were primary targets of the FCTC, it is fair to say that, 11 years after the FCTC came into force, it has not proven to be a stellar success on its own terms.⁶

Ver Bilano, Stuart Gilmour, Trevor Moffiet, Edouard Tursan d'Espaignet, Gretchen A Stevens, Alison Commar, Frank Tuyl, Irene Hudson, Kenji Shibuya, "Global trends and projections for tobacco use, 1990-2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control," The Lancet, Volume 385, No. 9972, pp. 966–976, 14 March 2015. DOI: http://dx.doi.org/10.1016/S0140-6736(15)60264-1

A survey of tobacco use conducted between 2008 and 2010 in 16 of the largest poor and middle income countries found that approximately 41% of adult men and 5% of adult women in those countries smoke. Gary Giovino et al. (The GATS Collaborative Group), "Tobacco use in 3 billion individuals from 16 countries: an analysis of nationally representative cross-sectional household surveys," The Lancet, Vol. 380, Issue 9842, pp. 668–679, 18 August 2012.

Did the FCTC Learn from the Lessons of Richer Countries?

Smoking rates in most wealthy countries peaked between the 1950s and 1970s (typically, rates peaked earlier for men, later for women) and have been falling since then. On average, rates of smoking in OECD countries fell by about 30% between 1990 and 2010 (only in Russia did smoking increase).

Since cigarette consumption has been falling for decades in richer countries, it would seem logical to consider what caused that decline. Broadly speaking, studies have found that in most countries the main drivers of reduced smoking rates have been some combination of: (1) increased public awareness of the dangers associated with smoking, (2) an increase in the price of cigarettes (including taxes), and (3) the availability of assistance for those who wish to quit smoking.⁸

In some countries, however, demand for cigarettes has fallen as a result of smokers switching to less harmful products, such as snus and vapor products. Snus is a form of oral tobacco that is pasteurized and kept refrigerated, thereby dramatically reducing levels of harmful chemicals compared with most other forms of oral tobacco. In 2003, the *Journal of Internal Medicine* published a study by Dr. Brad Rodu of the School of Medicine at the University of Alabama at Birmingham and colleagues from the Department of Medicine at University Hospital in Umea, Sweden, that evaluated data on rates of smoking and snus use among men and women in Northern Sweden derived from a series of World Health Organization surveys. They found that:

Amongst men ever-tobacco use was stable in all survey years at about 65%, but the prevalence of smoking declined from 23% in 1986 to 14% in 1999, whilst snus use increased from 22% to 30%. In women the prevalence of smoking was more stable in the first three surveys

OECD, OECD Factbook 2013: Economic, Environmental and Social Statistics; Health; Risk Factors; Smoking; Change in Smoking Rates, (Paris: Organization for Economic Cooperation and Development, 2013). Available at: http://dx.doi.org/10.1787/888932710745, accessed 2/26/2014.

In the U.S. context, a very careful meta-analysis undertaken by economist Jon Nelson, which combined analyses from dozens of previous studies, found that the most important factors influencing the decline in smoking in the U.S. were: health reports in 1953 linking smoking with lung cancer, the 1964 Surgeon General Report (which concluded that tobacco increases the likelihood of dying from various diseases), and anti-smoking advertisements from 1967 to 1970 that were broadcast without charge to the producers (which included the American Cancer Society) under the FTC's "fairness doctrine." See: Jon P. Nelson, "Cigarette Advertising Regulation: A Meta-Analysis," *International Review of Law and Economics*, Vol. 26(2), 2006, pp. 195–226. In the Australian context, economists Peter Bardsley and Nilss Olekalns found that "Over the past 35 years, price (including tobacco taxes), real income, and demographic effects explain most of the variation in tobacco consumption [in Australia]." See: Peter Bardsley and Nilss Olekalns, "Cigarette and Tobacco Consumption: Have Anti-Smoking Policies Made a Difference?" *The Economic Record*, Vol. 75, issue 230, 1999, pp. 225–240.

Much of the toxicity of conventional oral tobacco comes from compounds, such as tobacco-specific nitrosamines, that are produced by bacteria growing on the tobacco; pasteurization kills these bacteria and refrigeration inhibits their growth.

(approximately 27%) but was 22% in 1999, when snus use was 6%. In all years men showed higher prevalence of ex-smoking than women. A dominant factor was a history of snus (PR = 6.18, CI = 4.96-7.70), which was more prevalent at younger ages.

The following year (2003), *Tobacco Control* published a study by Dr. Jonathan Foulds, then at the Tobacco Dependence Institute of the University of Medicine and Dentistry in New Jersey, and three co-authors, that reviewed the effect of snus use in Sweden and concluded that:

Snus ...is dependence forming, but does not appear to cause cancer or respiratory diseases. It may cause a slight increase in cardiovascular risks and is likely to be harmful to the unborn fetus, although these risks are lower than those caused by smoking. 10

Moreover, Foulds et al. noted that as a result of increased use of snus in Sweden:

There has been a larger drop in male daily smoking (from 40% in 1976 to 15% in 2002) than female daily smoking (34% in 1976 to 20% in 2002) in Sweden, with a substantial proportion (around 30%) of male ex-smokers using snus when quitting smoking. Over the same time period, rates of lung cancer and myocardial infarction have dropped significantly faster among Swedish men than women and remain at low levels as compared with other developed countries with a long history of tobacco use.

In other words, as of 2003, snus use had dramatically reduced the use of combustible tobacco and associated tobacco-related diseases in Sweden. So one would think that the WHO in general and the FCTC in particular would have been very enthusiastic about the potential for snus and other harm reduction products. Indeed, the Convention itself supports harm reduction, stating: "tobacco control' means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke "11

But while the WHO has been strongly supportive of harm reduction in other contexts—for example, advocating methadone substitution and the use of condoms to reduce HIV transmission—it has been far less supportive when it comes to tobacco. 12 For example, in 2006, three years after the seminal study by Foulds et al, the WHO released a document titled *Tobacco: Deadly in Any Form or Disguise* in which it asserted that: "It is worth noting that, despite the differences in relative health risks compared with other tobacco products, a recent review of smokeless tobacco by the International

Jonathan Foulds, Lars Ramstrom, M. Burke, Karl Fagerström, "Effect of smokeless tobacco (snus) on smoking and public health in Sweden," Tobacco Control, 2003, Vol. 12, pp. 349–359.

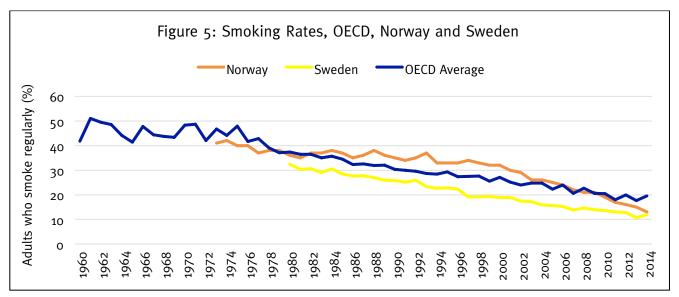
World Health Organization, WHO Framework Convention on Tobacco Control, Geneva: World Health Organization, 2003, Article 1.

See, for example: WHO Regional Office for the Western Pacific, Priority HIV and sexual health interventions in the health sector for men who have sex with men and transgender people in the Asia-Pacific Region, Geneva: World Health Organization, 2010. And also: http://www.wpro.who.int/hiv/topics/key_populations/en/index2.html

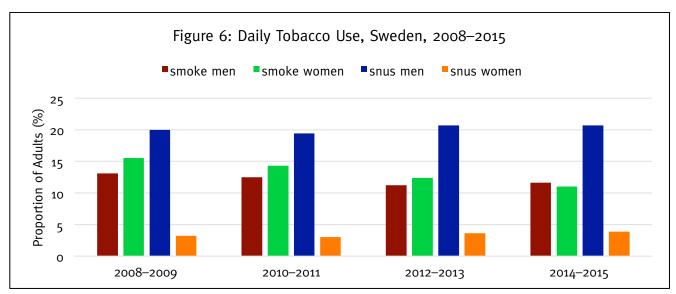
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Agency for Research on Cancer concluded that smokeless tobacco is carcinogenic, making no exception for Swedish snus."¹³

Since 2003, Swedish smokers have continued to switch to snus—and smoking rates in the country have continued to decline. Moreover, snus use in Norway has contributed to a more rapid decline in that country also. These trends in smoking for Sweden and Norway, compared with the OECD average, can be clearly seen in Figures 5, 6 and 7.



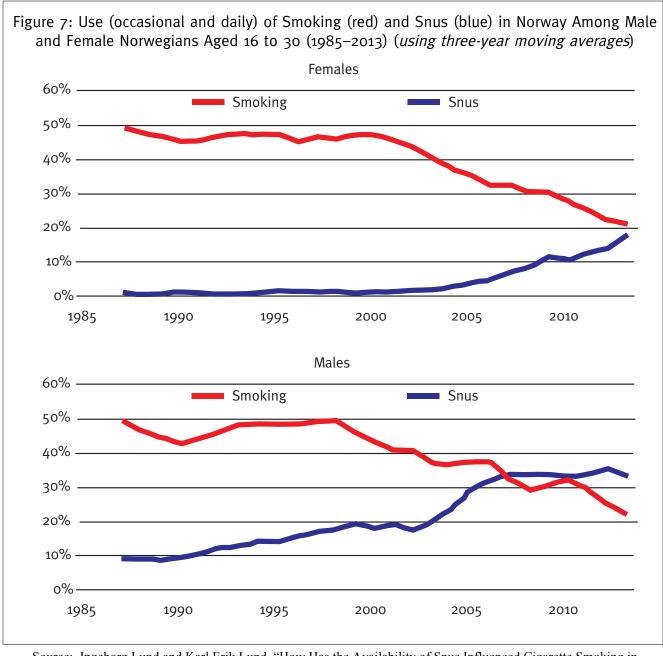
Source: Data from OECD (https://data.oecd.org/healthrisk/daily-smokers.htm)



Source: Data from: Statistics Sweden

 $(http://www.statistikdatabasen.scb.se/pxweb/en/ssd/START_LE_LE0101_LE0101H/LE0101H28/?rxid=bf3fc07c-6c58-4a98-932d-bc8eab51dcd0)$

World Health Organization, *Tobacco: Deadly in Any Form or Disguise*, (Geneva: World Health Organization, 2006), at p. 27.

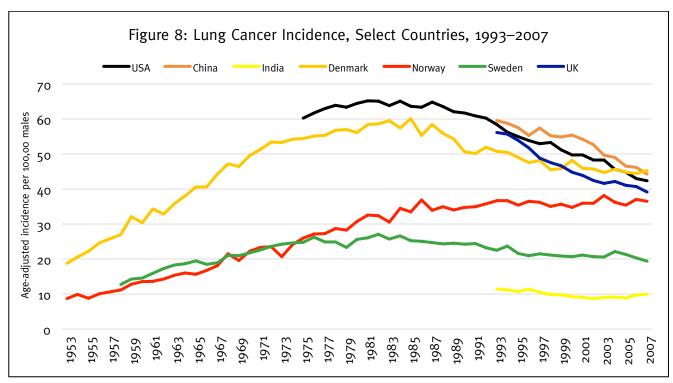


Source: Ingeborg Lund and Karl Erik Lund, "How Has the Availability of Snus Influenced Cigarette Smoking in Norway?" International Journal of Environmental Research and Public Health, Vol. 11(11), pp. 11705–11717, 2014.

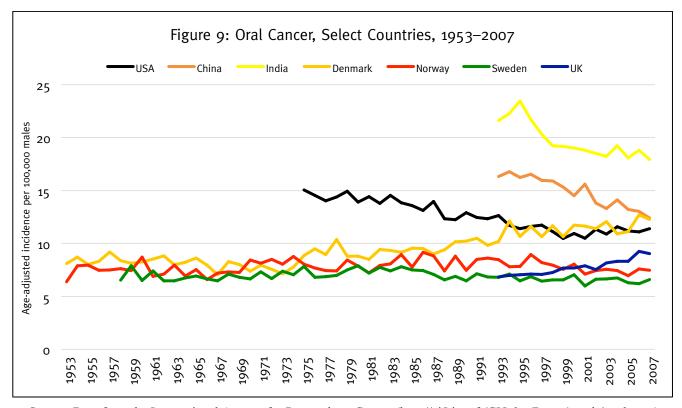
As Figure 8 shows, the incidence of lung cancer among men peaked earlier in Sweden than in other countries. Indeed, by 2002, Sweden had the lowest lung cancer rate in the European Union.¹⁴ This came about largely as a result of the lower incidence of smoking in Sweden, which in turn is in part attributable to the switch to use of snus. In Norway, lung cancer rates continued to rise for longer because snus use was less popular and only rose dramatically in the past 20 years. Meanwhile, as

Brad Rodu and Philip Cole, "Lung cancer mortality: Comparing Sweden with other countries in the European Union," Scandinavian Journal of Public Health, 2009, Vol. 37, pp. 481–486.

Figure 9 shows, the incidence of oral cancer has consistently been lower in Sweden and Norway than other countries.



Source: Data from the International Agency for Research on Cancer (http://ci5.iarc.fr/CI5plus/Pages/graph4 sel.aspx)



Source: Data from the International Agency for Research on Cancer (http://ci5.iarc.fr/CI5plus/Pages/graph4_sel.aspx)

In addition to this mounting evidence of the relative safety of snus use compared to smoking, a large literature has developed specifically on the safety of nicotine. This is summarized by Konstantinos Farsalinos, Professor of Cardiology at the University of Athens, and Riccardo Polosa, Director of the Center for the Prevention and Cure of Tobacco Related Disease at the University of Catania in Italy, who state, bluntly, "nicotine does not contribute to smoking-related diseases." They continue:

[Nicotine] is not classified as a carcinogen by the International Agency for Research on Cancer and does not promote obstructive lung disease. A major misconception, commonly supported even by physicians, is that nicotine promotes cardiovascular disease. However, it has been established that nicotine itself has minimal effect in initiating and promoting atherosclerotic heart disease. It does not promote platelet aggregation, does not affect coronary circulation and does not adversely alter the lipid profile. An observational study of more than 33,000 smokers found no evidence of increased risk for myocardial infarction or acute stroke after NRT [nicotine replacement therapy] subscription, although follow up was only 56 days. Up to 5 years of nicotine gum use in the Lung Health Study was unrelated to cardiovascular diseases or other serious side effects. A meta-analysis of 35 clinical trials found no evidence of cardiovascular or other life-threatening adverse effects caused by nicotine intake. Even in patients with established cardiovascular disease, nicotine use in the form of NRTs does not increase cardiovascular risk.

In 2012, the Secretariat of the FCTC published a report on smokeless tobacco products prior to the Fifth Conference of the Parties, in which it stated:

Arguments are being put forward that certain low nitrosamine SLT [smokeless tobacco] products can be used by smokers as alternatives to cigarettes. In this regard, two primary concerns emerge: (1) encouragement of novices (particularly young people) to take up SLT use, including the more toxic forms; and (2) dual use of cigarettes and SLT. A commonly expressed concern is that young people may be attracted to SLT products, but eventually move to use of cigarettes and other tobacco products (i.e. SLT can act as a "gateway" to smoking). Dual or simultaneous use of cigarettes and SLT could sustain nicotine addiction, delay cessation and contribute to a compensation of the reduced quantity of cigarettes smoked. Another related concern is that if smokers turn to SLT when they are unable to smoke, the effect of smoking bans on encouraging smoking cessation may be diminished. Dual users tend to have higher nicotine dependence, and although it is unclear whether this is an antecedent or consequence of dual use, it poses a public health challenge. 16

World Health Organization, Control and prevention of smokeless tobacco products. Report by the Convention Secretariat, Conference of the Parties to the WHO Framework Convention on Tobacco Control, fifth session, Seoul, Republic of Korea, 12–17 November 2012, FCTC/COP/5/12, 10 July 2012.

Konstantinos E. Farsalinos and Riccardo Polosa, "Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review," *Therapeutic Advances in Drug Safety*, 2014, Vol. 5(2), pp. 67–86.

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In other words, in spite of the overwhelming evidence that low nitrosamine smokeless tobacco products (i.e. snus) have resulted in (a) a dramatic reduction in smoking in those countries where they are widely available and culturally acceptable, and (b) a similarly dramatic decline in tobacco-related disease, the WHO felt that it was appropriate to raise concerns that either were contradicted by the evidence (the alleged "gateway" to smoking effect and delayed or diminished cessation), are of little material concern (continued addiction to nicotine—a substance that is not considered harmful to most users), or could result in greater harm ("contribute to compensation of the reduced quantity of cigarettes smoked"; the implication being that it is better for people to smoke more than to combine use of snus with smoking, even though the latter would reduce users' exposure to tobacco smoke and hence the likelihood that they will suffer from tobacco-related diseases).

In general, the WHO demands an excessively high standard of evidence for new products. In *Tobacco: Deadly in Any Form or Disguise* it asserted: "For new products and for those under development, additional research is needed to understand more precisely whether their risks are the same as the products they would replace. Such research will take years, or even decades. Until such research is completed, the most prudent course is to assume that their health risks are extraordinarily high compared with any ordinary consumer product and to make every effort to prevent their use along with all other tobacco products." Given that decades of data were already available on the effects of snus by the time the WHO published this, one wonders if any amount of data will ever be sufficient to persuade it of the merits of harm reduction products.

Perhaps unsurprisingly, the WHO has applied this approach to vape products. For example, in 2013 it tweeted "Until e-cigarettes are deemed safe, approved by competent national regulatory body, consumers should be strongly advised not to use them." At the conclusion of the sixth Conference of the Parties to the Framework Convention on Tobacco Control, in October 2014, the FCTC Secretariat issued a press release stating that:

Another milestone in tobacco control was adoption of the decision on electronic nicotine (and non-nicotine) delivery systems [ENDS or ENNDS], also known as electronic cigarettes. This rather novel product was first launched by independent companies, but many of them are now being controlled by multinational tobacco companies. The decision acknowledges the need for regulations along the lines of policies concerning other tobacco products, including banning or restricting promotion, advertising and sponsorship of ENDS. ¹⁸

¹⁷ Ibid, at pp. 37–38.

World Health Organization, *News release: WHO tobacco treaty makes significant progress despite mounting pressure from tobacco industry*, 18 October 2014, Available at: http://www.who.int/mediacentre/news/releases/2014/cop6-tobacco-control/en/, accessed 8/9/2016.

This is a misrepresentation of the Decision that was taken, which states that it "INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health." In other words, the parties meeting actually were not committed specifically to regulating the devices, "along the lines of policies concerning other tobacco products" but rather offered a wide range of possible forms of regulation, including as consumer products. The blatant misrepresentation of the Decision language is, however, indicative of the bias shown by the WHO against tobacco harm reduction in general and vape products in particular.

Conference of the Parties to the WHO Framework Convention on Tobacco Control, sixth session, Moscow, Russian Federation, 13–18 October 2014, *DECISION FCTC/COP6(9) Electronic nicotine delivery systems and electronic non-nicotine delivery systems*, 18 October 2014. Available at: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6(9)-en.pdf, accessed 8/9/2016.

Quit or Die: A Deadly Disease

What is driving this hostility to tobacco harm reduction? Probably the most important reason is that many people in the public health community seem to believe that harm reduction is not possible when it comes to tobacco. This belief seems to have its roots in earlier failed attempts to produce "safer cigarettes": Beginning in the 1960s, public health advocates, governments and tobacco companies sought to develop cigarettes that would deliver the smoking experience with fewer adverse health effects. However, the innovations that resulted either did not provide significant health benefits or were not commercially successful. As a result, by the 1990s, many in the public health community had abandoned the idea that harm reduction was possible.

If this were 1986 or even 1996, such a perspective might be intellectually defensible. However, by 2006, the evidence of snus's benefits were clear; in 2016, that evidence has become incontrovertible. Meanwhile, there is now very solid evidence that vape products are both far, far safer than cigarettes and are resulting in a significant reduction in smoking.²⁰ (These products were developed largely by small companies and individuals, most of whom had no connection to traditional tobacco companies they were never part of the project to develop a "safer cigarette." As such, the WHO's opposition to tobacco harm reduction is dishonest and threatens public health.

Second, the WHO might be responding to pressure from vested interests. Numerous companies apparently benefit from the status quo. Tobacco companies that have not developed harm reduction products would be at a competitive disadvantage if smokers switched to less harmful alternatives. Pharmaceutical companies selling drugs that help smokers to quit would likely experience lower sales if smokers choose to continue consuming nicotine. And pharmaceutical companies selling nicotine replacement therapy might experience lower sales as a result of smokers having a wider range of substitutes available.

Third, as its 2008 Report on the Global Tobacco Epidemic makes clear, the WHO conceives of tobacco itself as a disease (it literally refers to "the tobacco epidemic," 22) and views "The tobacco industry as

See e.g. Royal College of Physicians, Nicotine without smoke: Tobacco Harm Reduction, A report by the Tobacco Advisory Group of the Royal College of Physicians, (London: Royal College of Physicians, 2016); Parliamentary Office of Science and Technology, Electronic Cigarettes, London: Houses of Parliament, POSTNOTE Number 533, August 2016; and Julian Morris and Amir Ullah Khan, The Vapour Revolution, (Los Angeles: Reason Foundation, 2016).

Morris and Khan, The Vapour Revolution.

World Health Organization, WHO Report on the Global Tobacco Epidemic, 2008: The MPOWER Package, Geneva: WHO (contains 27 references to "the tobacco epidemic"). See also: World Health Organization, Tobacco Deadly in Any Form or Disguise, (Geneva: World Health Organization, 2006), at p. 11; World Health Organization, WHO Report on the Global Tobacco Epidemic, 2011: Warning about the dangers of tobacco, (Geneva: WHO, 2011); World Health Organization, WHO Report on the Global Tobacco Epidemic, 2013: Enforcing bans on tobacco advertising, promotion and sponsorship, (Geneva: WHO, 2013).

[the] disease vector," claiming that "Tobacco companies have long targeted youth as 'replacement smokers' to take the place of those who quit or die."23 Thus, the WHO has chosen to focus its efforts on eliminating tobacco use, rather than reducing the harm done by tobacco, and to that end it states:

To expand the fight against the tobacco epidemic, WHO has introduced the MPOWER package of six proven policies:

- *Monitor tobacco use and prevention policies,*
- Protect people from tobacco smoke,
- Offer help to quit tobacco use,
- Warn about the dangers of tobacco,
- Enforce bans on tobacco advertising, promotion and sponsorship, and
- Raise taxes on tobacco.

The WHO has set its store by this approach, investing heavily in its promotion. So, even though substitution with less harmful products is also a proven and important complementary means of quitting or reducing smoking and the diseases associated with smoking, the WHO, having chosen not to include such harm reduction in its toolkit, is reluctant even to acknowledge it. By seeking to curtail or ban these less harmful alternatives to smoking, the FCTC positions itself squarely against smokers and former smokers trying to improve their health while retaining the pleasurable rituals of their habit, as well as companies seeking to produce the less harmful products that would help them to do so.

Whatever the cause(s), the result is that the WHO and its allies in the public health movement, health ministries, and companies have aggressively pursued an approach that is aptly named, by its advocates, "quit or die": smokers either quit, or risk dying of diseases related to smoking. Harm reduction is not an option. This is deeply troubling. It is also deadly, since it denies smokers—those who cannot or do not want to stop consuming relatively harmless nicotine—alternative and less harmful ways to continue their habit without the damaging health effects of combustible tobacco. It effectively consigns to death millions of smokers who would have chosen these less harmful alternatives but are unable to do so because governments have restricted their availability on the advice of the WHO.

If "tobacco" is a disease, then so is the WHO's fanatical adherence to the "quit or die" ideology and consequent opposition to tobacco harm reduction, since it almost certainly will result in more people dying from smoking. And the disease vector is the FCTC, which the WHO uses to push its "six proven policies" to the exclusion of harm reduction.

World Health Organization, WHO Report on the Global Tobacco Epidemic, 2008: The MPOWER Package.

The WHO's Deadly Opposition to Consumer Choice Contradicts Its Constitution, the Declaration of Alma Ata, and the Ottawa Charter

The preamble to the Constitution of the World Health Organization states that "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."²⁴ This is instantiated in Article 1 of that Constitution, which states: "The objective of the World Health Organization (hereinafter called the Organization) shall be the attainment by all peoples of the highest possible level of health."25

In 1978, the WHO organized a meeting in Alma Ata (now in Kazakhstan; then part of the Soviet Union), at which it issued a Declaration on primary health care. In that Declaration, it noted that primary health care, "requires and promotes maximum community and individual self-reliance and participation in the planning, organization, operation and control of primary health care..." As John Catford, editor of Health Promotion International, has noted, "Alma Ata heralded a shift in power from the providers of health services to the consumers of those health services and the wider community."²⁷

In November 1986, the WHO organized a conference in Ottawa, Canada, at which it issued a Charter on Health Promotion. The opening sentence of that Charter states: "Health promotion is the process of enabling people to increase control over, and to improve, their health."²⁸ Later on, it reaffirms this, stating: "People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health."²⁹

WHO, Constitution of the World Health Organization, (Geneva: World Health Organization, 1948). The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States and entered into force on 7 April 1948.

Constitution of the World Health Organization, (Geneva: World Health Organization, 1948).

World Health Organization, Declaration of Alma-Ata, International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978.

John Catford, "Ottawa 1986: back to the future," Health Promotion International, Vol. 26 (suppl 2): ii, pp. 163–167, 2011. doi: 10.1093/heapro/dar081.

World Health Organization, The Ottawa Charter for Health Promotion, First International Conference on Health Promotion, Ottawa, 21 November 1986. Text available at: http://www.euro.who.int/ data/assets/pdf file/0004/129532/Ottawa Charter.pdf, accessed 9/8/2016.

Ibid.

In a document prepared for the upcoming Conference of the Parties (COP) in India in November 2016, the FCTC asserts that "As an evidence-based treaty that reaffirms the right of all people to the highest attainable standard of health, the Convention not only acknowledges the relationship between tobacco use and human rights, it also explicitly references previously constructed international human rights conventions, and enshrines those principles within its text." It then goes on to cite some examples of the application of these principles, including "the right to be protected from exposure to tobacco smoke, as set forth in Article 8, and the right to access the information necessary to make healthy choices, as established in many provisions of the Convention."

Yet, the WHO has to date, both directly and through the FCTC, sought to limit access to harm reduction technologies that would enable smokers more effectively to take control of one thing that is potentially a very significant determinant of their health—smoking. So, while the FCTC Secretariat may pay lip service to human rights, it does not appear to take seriously the relationship between human rights and health as recognized in earlier foundational documents of the WHO. (The Secretariat's blasé repudiation of highly effective harm reduction products also contradicts the claim that the FCTC is "evidence-based.")

Moreover, the FCTC Secretariat's support for "banning or restricting promotion, advertising and sponsorship of ENDS," contradicts the claim that it respects, "the right to access the information necessary to make healthy choices."

FCTC Secretariat, International cooperation for implementation of the WHO FCTC, including implementation of the 2030 Agenda for Sustainable Development, the global NCD targets and human rights. Report by the Convention Secretariat, Conference of the Parties to the WHO Framework Convention on Tobacco Control, seventh session, Delhi, India, 7–12 November 2016, Provisional agenda item 6.2, FCTC/COP/7/16, 27 June 2016.

World Health Organization, *News release: WHO tobacco treaty makes significant progress despite mounting pressure from tobacco industry*, 18 October 2014, Available at: http://www.who.int/mediacentre/news/releases/2014/cop6-tobacco-control/en/, accessed 8/9/2016.

FCTC: A Governance Failure

Underlying the FCTC's abrogation of human rights is a governance structure that violates many of the core precepts of good governance as spelled out by the United Nations Development Program:³²

- Participation: All men and women should have a voice in decision making, either directly or through legitimate intermediate institutions that represent their interests. Such broad participation is built on freedom of association and speech, as well as capacities to participate constructively.
- Rule of law: Legal frameworks should be fair and enforced impartially, particularly the laws on human rights.
- Transparency: Transparency is built on the free flow of information. Processes, institutions and information are directly accessible to those concerned with them, and enough information is provided to understand and monitor them.
- **Responsiveness:** Institutions and processes try to serve all stakeholders.
- Consensus orientation: Good governance mediates differing interests to reach a broad consensus on what is in the best interests of the group and, where possible, on policies and procedures.
- **Equity:** All men and women have opportunities to improve or maintain their well-being.
- Effectiveness and efficiency: Processes and institutions produce results that meet needs while making the best use of resources.
- Accountability: Decision-makers in government, the private sector and civil society organisations are accountable to the public, as well as to institutional stakeholders. This accountability differs depending on the organisation and whether the decision is internal or external to an organisation.
- Strategic vision: Leaders and the public have a broad and long-term perspective on good governance and human development, along with a sense of what is needed for such development. There is also an understanding of the historical, cultural and social complexities in which that perspective is grounded.

UNDP, Governance for Sustainable Human Development: A UNDP Policy Document, (Geneva: United Nations Development Program, 1997). Available at: http://www.pogar.org/publications/other/undp/governance/undppolicydoc97-e.pdf, accessed 9/5/2016.

The UNDP goes on to note that:

[T] hese core characteristics are mutually reinforcing and cannot stand alone. For example, accessible information means more transparency, broader participation and more effective decision-making. Broad participation contributes both to the exchange of information needed for effective decision making and for the legitimacy of those decisions. Legitimacy, in turn, means effective implementation and encourages further participation. And responsive institutions must be transparent and function according to the rule of law if they are to be equitable.

First, while the FCTC does have a formal process for engaging stakeholders, it does not meet the UNDP's standards for "participation," "responsiveness" and "consensus orientation" because it is insufficiently broad and specifically excludes important groups of people affected by its decisions.

Articles 29, 30 and 31 of the FCTC's Rules of Procedure permit certain "Observers" to "participate without the right to vote in public or open meetings of the Conference of the Parties and of its subsidiary bodies." The rules state that Observers are also permitted to "speak" during open or public meetings of the Conference of the Parties (COPs) and subsidiary bodies. This gives the appearance that the FCTC is extremely participatory—more so than most other intergovernmental agreements. 35

But actual, permitted participation in the FCTC is extremely narrow. The FCTC currently lists only 20 NGOs as Observers on its website. By contrast, the Framework Convention on Climate Change lists over 2,000 NGOs as Observers on its website. Moreover, there is essentially no participation by representatives of many affected groups, including users of tobacco and vape products, wendors, and farmers. Participation by IGOs has also been restricted; even Interpol has been denied Observer status, despite its expertise in combating illicit trade in tobacco—a key topic covered by the Convention.

http://unfccc.int/parties and observers/ngo/items/9411.php

FCTC, Rules of Procedure of the Conference of the Parties, 2014 Edition, (Geneva: World Health Organization, 2014).

Permission to speak is given in the following order of priority: (1) member states that are not party to the Convention, (2) intergovernmental organizations (IGOs), and (3) nongovernmental organizations (NGOs).

See e.g. J. Borrie and V. Martin Randin (eds), *Alternative Approaches in Multilateral Decision Making: Disarmament as Humanitarian Action*, (Geneva, United Nations: UNIDIR, 2005), p. 106.

http://www.who.int/fctc/cop/observers_ngo/en/

Several vape user groups have refused even to seek Observer status because the FCTC requires them to sign up to all of its objectives, some of which they find objectionable and hostile to the FCTC's interests. (Personal communication with representatives of vape groups, June-August 2016.)

A major farmer group, the International Tobacco Growers Association, applied for Observer status in 2016 but was denied.

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Second, as already noted, laws on human rights have been applied in a biased and inconsistent manner. In particular, the FCTC's repudiation of harm reduction products that are already being used by millions of people is a clear violation of the rights of those people to improve their own health, of others who might choose to use such technologies, and of those who are currently subjected to tobacco smoke, who otherwise might not be so exposed.

Third, the FCTC is distinctly lacking when it comes to transparency. In addition to formal "Observers," the FCTC has since its inception permitted attendance of public sessions by media and others in the public gallery. However, at COP5, in Seoul, Korea, when the COP broke into committees, the chair "proposed that, in view of the concerns expressed by delegations regarding the large presence of the tobacco industry in the public gallery, the Committee should work in closed session." So the public gallery was cleared and the committee met in secret. At COP6, the same routine was followed. In each case, everyone in the public gallery was ejected—including all journalists—and the meeting proceeded essentially in secret.

Beyond the COPs, the processes by which decisions are taken and documents are produced are shrouded in secrecy. For example, at COP6, parties to the FCTC decided to commission "an expert report, with independent scientists and concerned regulators, for the seventh session of the Conference of the Parties with an update on the evidence of the health impacts of ENDS/ENNDS, potential role in quitting tobacco usage, impact on tobacco control efforts and to subsequently assess policy options ..." The decision to commission such a report was not in itself problematic (notwithstanding the fact that the decision was taken during a session that had been closed to the public). However, the process by which experts were selected to produce the report has not been disclosed.

The Report on ENDS/ENNDS was released on the FCTC's website on September 8, 2016, just two months before it is to be discussed at the forthcoming COP in India. It does not disclose the authors but it states that it, "incorporates the December 2015 deliberations and scientific recommendations on ENDS/ENNDS by the WHO Study Group on Tobacco Product Regulation (TobReg) at its eighth meeting (Rio do Janeiro, Brazil, 9–11 December 2015), the May 2016 informal consultation on policy options held in Panama (4–5 May 2016, Panama City, Panama) and four background papers commissioned by WHO." The two meetings referenced were held in secret and the four background papers are not publicly available.

FCTC, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Fifth Session, Seoul, Republic Of Korea, 12–17 November 2012, Summary Records Of Committees, (Geneva: World Health Organization, FCTC/COP/5/REC/2, 2012).

World Health Organization, *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems* (ENDS/ENNDS): Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control Seventh Session, Delhi, India, 7–12 November 2016, Provisional agenda item 5.5.2 FCTC/COP/7/11, August 2016.

Perhaps unsurprisingly, the Report does not exactly offer a ringing endorsement of vapor products. Its review of evidence is both partial and biased. For instance, when discussing the potential for ENDS/ENNDS to initiate youth in nicotine use and smoking, it discusses trend data of use of vape products in several countries but ignores the evidence that increases in use of vape products have been associated with *reduced* smoking initiation. ⁴² Meanwhile, when it comes to regulatory options, it makes a range of suggestions, many of which would result in severe restrictions on the availability of vape products. Such restrictions would almost certainly result in fewer people switching from smoking to vaping—and, hence, more people smoking.

The FCTC's lack of transparency is worrying. The fact that this secrecy is being used to reinforce an apparent hostility to new, less harmful products in general and vape products in particular is disturbing.

Fourth, the FCTC may have a long-term vision but that vision is not grounded in an understanding of historical, social and cultural complexities: It ignores the fact that people in many cultures have been using tobacco products for hundreds of years, that social bonds have been formed and maintained around its use, and that—therefore—for many individuals and groups, availability of safer alternatives represents a more viable option than prohibition.

Fifth, FCTC's top-down approach to restricting supply and subsidizing alternative products is extremely costly—and is not effective, as demonstrated by the continued increase in tobacco consumption, especially in China and India.

Finally, the FCTC is not equitable: it has been hostile to the interests of people seeking to use less harmful products—snus and vaping—and it is hostile to almost all those who are involved in the production, distribution and sale of nicotine-containing products, from tobacco farmers to vape shop assistants.

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See the evidence presented in Morris and Khan, *The Vapour Revolution*, (Los Angeles: Reason Foundation, 2016).

Preventing Undue Influence

When it comes to setting policies, governments should, so far as possible, act impartially and seek to avoid being unduly influenced by any group. This cuts to the heart of "good governance." Achieving this ideal is another matter. The challenge is to achieve adequate participation, transparency, equity, and so on, while ensuring that particular groups that might benefit or be harmed by a particular policy are not able to push an agenda that is antithetical to the broader interests of society.

To address this concern, the parties negotiating the FCTC came up with a novel solution that is embodied in Article 5.3 of the Convention:

In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.

On the face of it, Article 5.3 is perfectly reasonable. It does not dictate specifically how any government should address the problem of undue influence, but rather encourages each government to identify solutions that are consistent with its governance framework. Nonetheless, in 2008, the FCTC produced a set of "guidelines" on the implementation of Article 5.3. These begin with a set of four "principles": 43

Principle 1: There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests.

Principle 2: Parties, when dealing with the tobacco industry or those working to further its interests, should be accountable and transparent.

Principle 3: Parties should require the tobacco industry and those working to further its interests to operate and act in a manner that is accountable and transparent.

Principle 4: Because their products are lethal, the tobacco industry should not be granted incentives to establish or run their businesses.

FCTC, Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry, (Geneva: World Health Organization Framework Convention on Tobacco Control, 2008). Available at: http://www.who.int/fctc/guidelines/article 5 3.pdf, accessed 9/8/2016.

From these "principles" then flow various "recommendations." Some of these are perfectly reasonable but others are at best peculiar. Consider recommendation 4.7:

Government institutions and their bodies should not have any financial interest in the tobacco industry, unless they are responsible for managing a Party's ownership interest in a State-owned tobacco industry.⁴⁴

Taken literally, this would require governments to stop imposing taxes on tobacco companies, which seems entirely contrary to key provisions of the FCTC, such as Article 6, which refers to the use of taxes on tobacco products in such a way as to reduce demand.

At the same time, it appears to absolve governments that actually own tobacco companies! Given that the most rapid increase in tobacco consumption is occurring in China, where the government-owned tobacco company has a virtual monopoly, this seems rather odd. To be fair, recommendation 8.1 states that where governments own tobacco companies, "Parties should ensure that the setting and implementing of tobacco control policy are separated from overseeing or managing tobacco industry." To think that this will happen, however, represents a triumph of hope over experience: With few exceptions, state-owned enterprises tend to be subjected to less onerous enforcement of regulations than private companies. A better approach would be for governments to sell their interests in tobacco companies and introduce appropriate tax and regulatory policies.

Other "recommendations" are unrelated to the purpose of Article 5.3. For example, recommendation 4.9:

Parties should not nominate any person employed by the tobacco industry or any entity working to further its interests to serve on delegations to meetings of the Conference of the Parties, its subsidiary bodies or any other bodies established pursuant to decisions of the Conference of the Parties.⁴⁷

Since Article 5.3 pertains specifically to the "setting and implementing" of Parties' *domestic* "public health policies with respect to tobacco control," it is unclear how this recommendation—which pertains to discussions in an international forum—can be justified. Moreover, the FCTC recognized that these guidelines are non-binding, but "encouraged" Parties to implement them: "Without prejudice to the sovereign right of the Parties to determine and establish their tobacco control policies, Parties are encouraged to implement these guidelines to the extent possible in accordance with their national law."

45 Ibid.

⁴⁴ Ibid.

See e.g. Erin Ryan, "The Elaborate Paper Tiger: Environmental Enforcement and the Rule Of Law In China," *Duke Environmental Law & Policy Forum*, Vol. 24, pp. 183–239; Magda Lovei and Bradford S. Gentry, *The Environmental Implications of Privatization: Lessons for Developing Countries*, (Washington, DC: The World Bank, 2002).

FCTC Guidelines for implementation of Article 5.3.

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And apparently the FCTC wishes to implement this particular recommendation regardless of whether Parties agree. It notes, in a document to be discussed at the forthcoming COP7, that "The Convention Secretariat initiated the inclusion of standard sentences aimed at preventing participation of delegates representing the tobacco industry or any entity seeking to further its interests in 2014, and tested such sentences in invitations issued in relation to technical meetings organized under the COP workplan."

These included, "in the case of technical meetings organized by the Convention Secretariat," the following: "In accordance with Article 5.3 of the WHO FCTC, the guidelines for implementation of Article 5.3 adopted by the COP in 2008, as well as relevant decisions of the COP, Parties are urged not to invite persons who represent the tobacco industry or entities working to further the interests of the tobacco industry as part of their delegations."

If the tobacco industry were indeed as nefarious as is claimed in Principle 1 of the guidelines, then perhaps it would be justifiable for Parties to the FCTC to agree to such onerous restrictions. But the reality is that the tobacco industry comprises many different companies, several of which are now explicitly committed to developing and marketing products that are far less harmful than conventional combustible cigarettes. And those companies have knowledge and experience of how most effectively to develop and market less harmful products to consumers, as well as the potential effects of policies on their ability and incentives to invest in further development and marketing of such products. Such insights might well be valuable to participants with a genuine interest in ensuring that people are able to achieve the highest attainable levels of health.

If participation by representatives of tobacco companies is beyond the pale, the proposed exclusion of "entities working to further the interests of the tobacco industry" surely goes too far as it offers the FCTC Secretariat almost carte blanche to exclude persons whose views do not conform with its own.

But even if exclusion of the tobacco industry were a worthwhile goal and even if the FCTC were able to exclude representatives of the tobacco industry from direct participation in COPs, technical meetings, and other bodies, it seems unlikely that it would be able to eliminate industry influence. Many governments receive significant revenue from tobacco production and/or taxes, so they have strong incentives to ensure that such revenue continues. However perverse those incentives are from a public health standpoint, they exist and must be acknowledged.

FCTC, "Maximizing transparency of Parties' delegations, intergovernmental organizations, nongovernmental organizations and civil society groups during sessions of the COP and meetings of its subsidiary bodies. Report by the Convention Secretariat," Conference of the Parties to the WHO Framework Convention on Tobacco Control, seventh session, Delhi, India, 7–12 November 2016, Provisional agenda item 7.9, FCTC/COP/7/30, 13 July 2016.

⁴⁹ Ibid.

The fact is, it is practically impossible to prevent corporations from interacting with government officials. According to John Stewart of Corporate Accountability International, during COP5, there were "tobacco industry representatives ... on at least four delegations: Zambia, Vietnam, Japan and China." Those representatives continued to participate in the meeting after other representatives—and all the journalists—were removed from the public gallery. Would it not be better for industry participation to be open and above board—declared for all to see—than driven underground?

Article 5.3 addresses only the interests of the "tobacco industry." But the "tobacco industry" is not the only entity with an interest in the outcome of the deliberations of the FCTC. As noted above, pharmaceutical companies have a strong interest in promoting their products. While some of these products have an important role to play in assisting people who want to quit smoking, they are no longer the only options for smokers wishing to quit or reduce their smoking. The commercial interests of some pharmaceutical companies are thus at odds with other producers of less harmful nicotine-containing products. Given that representatives of the pharmaceutical industry have been Observers of the FCTC, it is not inconceivable that they have sought to influence the FCTC's position on harm reduction products. ⁵¹

Unfortunately, as noted above, the FCTC has, for the past two COPs, excluded even the media from the public gallery, making it yet more difficult to discover which interests are being represented and what agendas are being pushed.

John Stewart, "Article 5.3: Protecting Against Industry Interference," *Bulletin of the Framework Convention Alliance*, Issue 122, Saturday, 17 November 2012.

The FCTC lists as Observers on its website: the International Federation of Pharmaceutical Manufacturers Associations, the International Pharmaceutical Federation, and the International Pharmaceutical Students Federation. See: http://www.who.int/fctc/cop/observers_ngo/en/, accessed 9/8/2016.

Curing the Disease: Making the FCTC More Open, Transparent, and Accountable

The WHO has acknowledged that "People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health," yet in the guise of the FCTC it has sought instead to promote only top-down solutions, fundamentally ignoring the potential for people to improve their own health by choosing less harmful alternatives to combustible tobacco products. It seems to have taken this approach in large part because of a presumption that "There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests." Yet the evidence suggests this is not correct.

The potential for people to improve their health by switching to less harmful products is enormous and many companies have a vested interest in enabling them to do so. Many of those companies have no connection to the traditional tobacco industry. But some very large tobacco companies are now also putting their weight behind less harmful products. For-profit companies have incentives to build and retain a customer base. To do so, they must be responsive to consumers' changing preferences. Given that consumers seem increasingly to prefer less harmful alternatives to cigarettes, tobacco companies seeking to remain in business will be compelled to develop and supply such alternatives. (It is also worth noting if their customers live longer, companies are likely to sell more products.) In the interest of enabling people to improve their health, the FCTC should embrace this approach.

If the FCTC is genuinely committed to the "right to health" then it must listen to those who are taking control of the things that determine their health—and to those who are helping them to do so. In other words, it should open itself up to participation by groups representing vapers, snus users, and companies producing these and other less harmful nicotine-containing products.

A more open, participatory FCTC would not produce papers in secret and make them available only a few weeks before COPs. Instead, it might issue a call for papers and encourage all parties with an interest in the issue to submit materials. It might then allow public scrutiny of those papers and form a committee, the composition of which is determined by votes from a much enlarged group of Observers, who can then review submissions and form conclusions.

At the same time, if the FCTC is genuinely concerned about avoiding conflicts of interest, then the best approach is to open itself up to scrutiny. That means, at the very least, permitting journalists to attend all sessions of COPs and technical committees. Better yet, the FCTC might livestream all its proceedings over the Web—in much the way that the Framework Convention on Climate Change livestreamed its 21st Conference of Parties.⁵²

In 2015 the Director General of the WHO, Margaret Chan, gave a speech at the Measurement and Accountability for Results in Health Summit in Washington, D.C., in which she stated, "Information is power. In this day and age where transparency is such a big commodity, there is no other option but to have transparency and accountability." Let's hope Dr. Chan lives up to her words during COP7 and opens up the FCTC to greater public scrutiny.

The webcast of these sessions is currently still available. See: http://unfccc6.meta-fusion.com/cop21/events/, accessed 9/8/2016.

Margaret Chan, "WHO Director-General's speech at the summit on measurement and accountability for results in health," Measurement and Accountability for Results in Health Summit, Washington, D.C., 9 June 2015.

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