

MASTERS IN LAW [LLM] DISSERTATION - 2007

Essay Title:

Emerging International Public Health Issues – Human Rights, Harm Reduction and the Framework Convention on Tobacco Control (FCTC).

Essay Type:

Long Essay – 15,000 words

Name of College:

King's College London

Name of Student:

Jeannie Cameron

Name of Supervisor:

Professor Roger Brownsword

Introduction

‘The last smoker stares hopelessly out at the rain. The last smoker is searching his pockets in vain. The smoke police are closing in - their sniffers never fail, if they detect a whiff of smoke the culprit goes to jail. The new people are clean living God fearing folk. They drink nothing that’s stronger than diet coke. They want to build a better world - they haven’t time to kill. They’d be ashamed to misbehave the way their parents did. The last smoker has taken his final toll, he’ll soon be dead and buried along with the very last joy. Gone are the Lucky Strikes that lovers shared. Goodbye to liberty in the land of the banned and the home of the scared.’¹

One of the most significant and controversial health issues of present times is the tobacco debate - opinions are strong and discussion is certainly guaranteed to divide a room – everyone has a view. Smokers are increasingly stigmatised, smoking bans, as the lyrics above would indicate are expected to increase; cigarette taxes (and smuggling) are rising, tobacco advertising is banned in most places in the world, health warnings on cigarette packets state very clearly that ‘smoking kills’ – and yet there are still over a billion people in the world who choose to smoke². The reasons no doubt vary and many are behavioural: addiction to nicotine, habit, image, enjoyment, peer pressure, and simple perceptions of ‘it’s sexy’ – there are both physical and mental dependence. Most economies in the world have also have a dependence on tobacco – for the excise taxes it generates (in the UK equal to 79% of a packet) and this adds to the complexity for governments needing to set appropriate health policies for the protection of the health of their citizens. This gives rise to public health rights - both to those who choose to smoke and those that do not wish to be exposed to tobacco smoke.

In mid-2006, Israeli High Court Justice, Justice Eli Rubinstein, granted an appeal in the case of *Irit Shemesh v. Fucachetta Ltd.*³ In effect, the judgment increased a nominal damages settlement for exposure by a pregnant woman to environmental tobacco smoke (ETS) in the workplace (without there being any injury sustained). He held that, in addition to criminal enforcement, there should be recognition within Israeli law for a mechanism of civil enforcement by a ‘caring citizen’ who sues for compensation from those who manage or own a public place but take no steps to prevent smoking in it. The judge cited the World Health

¹ Lyrics “The Last Smoker” [Landesman/Wallace] from “You can’t do that!” CD, Boisdale Blue Rhythm Band Copyright 2007, Boisdale Records.

² WHO statistics, www.who.org accessed 25 May 2007.

³ 2006 - CLA 9615/05, *Irit Shemesh v. Fucachetta Ltd.* rendered July 5, 2006 by the Supreme Court.

Organisation (WHO) Framework Convention on Tobacco Control (FCTC) treaty as the legal basis for his decision. Although the damages were fairly small⁴, an important precedent in international health law was created. Here was an international treaty, ratified by sovereign governments, being invoked in a groundbreaking domestic judgment involving an employer and an employee. Justice Rubinstein noted this when he said that “all the countries who ratified the FCTC have agreed that second hand smoke causes ‘death, disability and illness’ and are responsible for ‘protecting citizens from exposure to it.’”⁵ Many media commentators noted the significance of the Israeli verdict and anti-tobacco NGOs lauded the result as an outcome to be emulated elsewhere but there has been little corresponding analysis of some of the key questions that resulted from the verdict.

Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, states that ‘it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’, and the preamble to the Constitution of the WHO, 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’. The Israeli case focuses on the health rights of non-smokers not to be exposed to cigarette smoke in a workplace. This type of litigation is expected to increase as the FCTC is globally implemented, especially as the FCTC Guidelines on Exposure to Tobacco Smoke, aimed at assisting governments to implement their obligations under the treaty (which are premised on 100% smoke-free environments and a non-acceptance policy for ventilation solutions), are to be endorsed at the second meeting of the FCTC Conference of the Parties in July 2007.

While the rights of non-smokers seem well protected in the FCTC treaty and will be increasingly enabled in domestic law by Parties to the Convention, there is little the FCTC does for the protection of smokers rights – not necessarily the right to smoke (which is indirectly observed through the legality of the product to be traded and consumed),⁶ but the right of smokers who continue to smoke, despite knowing the risks, to have access to lower

⁴ *Israeli Insider*: Israeli Justice sets global precedent for anti-smoking rule enforcement 9 July 2006, <http://web.israelinsider.com/Articles/Briefs/8837.htm>. The compensation was increased tenfold, to 1000 Shekels plus legal fees and expenses, totalling 2,500 Shekels (about £350)

⁵ *Ibid*

⁶ Bhutan is the only country in the world where tobacco smoking is banned in one province.

risk products that are potentially less harmful to their health. The FCTC lacks the capacity to ensure that consumers are equipped with information on the relative risks so as to allow them to make informed health choices. There is no doubt that the most effective way to remove the harm from tobacco is to cease using it. But instead of taking a pragmatic view that many of the world's 1.3 billion smokers simply can't or won't quit and creating harm reducing policies and international law to accommodate that reality, the WHO FCTC stipulates that governments should make smokers quit and that the dependence on nicotine should be reduced through domestic cessation policies.

Before considering the missing concept of harm reduction, it is useful to look at where the FCTC came from and how it became such a political and policy force in the multilateral health context. The potted summary is an impressive one: after four years of negotiation by the 193 members of the WHO, the FCTC was unanimously adopted by the 56th World Health Assembly on 21 May 2003.⁷ After reaching the required 40 ratifications on 29 November 2004,⁸ it entered into force as international binding law for its contracting parties on 27 February 2005.

The idea for an international instrument for tobacco control was initiated in May 1995 at the 48th World Health Assembly (WHA) having initially been the subject of a discussion and exchange of ideas by two academics interested in law and public health⁹. The following year, the 49th WHA adopted resolution WHA49.17, requesting the WHO Director-General to initiate the development of a Framework Convention on Tobacco Control under the auspices of the WHO¹⁰ exercising for the first time its right to negotiate an international health treaty, contained in the WHO Constitution.¹¹ With this, the WHO's first treaty-making enterprise was formally launched. But it wasn't until 1999, a year after the then WHO Director-General,

⁷ The final text is contained in World Health Assembly Resolution 56.1.

⁸ WHO FCTC (adopted 21 May 2003, entered into force 27 February 2005) entered into force 90 days after it has been acceded to, ratified, accepted, or approved by 40 States.

⁹ (Ruth Roemer and Allyn Taylor) Global Tobacco Control Issues, Origins of the WHO FCTC, *American Journals of Public Health*, June 2005, Vol 95, No 6

¹⁰ In May 1999 the Fifty-second World Health Assembly paved the way for multilateral negotiations on the WHO FCTC and possible related protocols. Resolution WHA52.18 established two bodies to draft the framework convention, to complete negotiations and to submit the final text for consideration by the Fifty-sixth World Health Assembly.

¹¹ WHO Constitution, 22 July 1946, Article 19 – 'the Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the organisation... which shall come into force for each Member when accepted by it in accordance with its constitutional process.'

Dr Gro Harlem Brundtland, made global tobacco control a priority of the WHO, that work on the WHO Framework Convention on Tobacco Control began¹².

Before the FCTC entered into force, the then Director-General of the WHO, Dr Kim Wook Lee urged WHO members to:

‘...quickly sign and ratify the treaty...the WHO FCTC negotiations have already unleashed a process that has resulted in visible differences at country level. The success of the WHO FCTC as a tool for public health will depend on the energy and political commitment that we devote to implementing it in countries in the coming years. A successful result will be global public health gains for all.’¹³

Indeed WHO members did act quickly - the FCTC was open for signature for one year from 29 June 2003 and achieved 168 signatories in that time. ‘The treaty, which is now closed for signature, has 168 signatories, including the European Community, which makes it the most widely embraced treaty in UN history.’¹⁴ As of 20 June 2007, the FCTC had 148 Parties representing those that have ratified or acceded to it and therefore bound to implement tobacco control measures domestically according to the provisions outlined in the treaty. The speed at which the FCTC entered into force and its subsequent implementation into the domestic law of those countries that have become Parties is relatively unprecedented for a rights based treaty.

The FCTC is ‘an evidence based treaty that reaffirms the right of all people to the highest standard of health,’¹⁵ which makes it all the more remarkable that as the world’s first health treaty, which opens in its Preamble with a statement regarding the need to ‘give priority to the right to protect public health,’ fails to include anywhere in the text the need to protect public health by reducing the harm of tobacco products and/or devising regulation in support of the least harmful products. This is especially incongruous because the FCTC covers practically everything else. It provides regulatory guidance for governments in terms of supply reduction measures, such as the illicit trade in tobacco products¹⁶ and sales to and by children¹⁷; as well

¹² WHO Website <http://www.who.int/tobacco/framework/history/en/index.html>

¹³ Dr LEE Jong-wook. Director-General, World Health Organisation, August 2003

¹⁴ Forward to the FCTC ISBN 92 4 159101 3 WHO 2003,

¹⁵ Forward to FCTC

¹⁶ FCTC Article 15

¹⁷ FCTC Article 16

as demand reduction measures such as packaging and labelling of tobacco products¹⁸, and provision for tobacco advertising bans.¹⁹ Yet, of its entire 38 articles only two paragraphs are devoted to the tobacco product itself, and these deal only with the contents and emissions of tobacco products²⁰ and tobacco product disclosures²¹ – neither provide reference to regulation to reduce the harm of the tobacco product in pursuit of the protection of public health. While this anomaly ought to be the topic of global debate, both substantively and legally, there appears only to be one article written that remarks on this outcome:

‘While successful in its execution it fails to acknowledge the harm reduction strategies necessary to help those incapable of breaking their dependence on tobacco...the FCTC has created broad principles of normative consensus for international tobacco control, challenging the globalisation of smoking through the globalisation of tobacco control. WHO member states intend the broad obligations of the FCTC to be supplemented by several individualised protocols, which will develop specific governmental obligations for the respective aspects of tobacco control addressed by the FCTC. Despite this successful, albeit incremental, transnational approach to tobacco control, neither the FCTC nor any currently proposed protocols adequately addresses the subject of harm reduction with any specificity...the FCTC fails to place affirmative obligations on countries vis-à-vis harm reduction...as a result, the FCTC – the first treaty drafted explicitly to protect public health – has been criticised for lacking a firm basis in public health.’^{22 23 24}

While it is extraordinary that the focus and obligations contained in the world’s first health treaty appear to be in all areas other than health per se, perhaps this can be traced back to the novel process by which it was created – a process that has set international law precedents and has culminated in a multilateral treaty with more domestic penetration than most similar policy instruments. The constitutional law expert from the United States Justice Department on the United States FCTC negotiating delegation, who claims very clearly that he is not a fan of the tobacco industry,²⁵ published the following perspective in the *Chicago Journal of International Law* after the FCTC was adopted: ‘My personal view is that the FCTC is an

¹⁸ FCTC Article 11

¹⁹ FCTC Article 13

²⁰ FCTC Article 9

²¹ FCTC Article 10

²² Meier BM & Shelly D. The Fourth Pillar of the FCTC: Harm Reduction and the International Right to Health. Centre for Health Policy at Columbia University, Public Health Reports September-October 2006, volume 121

²³ Meier BM. Breathing new life in the Framework Convention on Tobacco Control: smoking cessation and the right to health. *Yale J Health Policy Law Ethics* 2005; 5: 137-92

²⁴ Williamson CH. Clearing the smoke: addressing the tobacco issue as an international body. *Penn State International Law Review* 2002; 20: 587-615

²⁵ Gregory F. Jacob – “Without Reservation” *Chicago Journal of International Law* Vol 5 No 1 Summer 2004

imperfect document produced by a deeply flawed process... as a member of the United States delegation that negotiated the FCTC, I observed first-hand the process by which the treaty was created.²⁶ In the article he strongly encourages the United States Government, whether it agrees to become a Party to the FCTC or not, to be careful of: ‘taking any action that might be seen as implicitly endorsing the underlying negotiation process or as sending a signal that the United States would be willing to participate in a similar negotiation process with respect to other treaties in the future’.²⁷

His concerns are not without foundation. The underlying legal rationale of international public law and the norms of inter-State relations, especially in the context of multilateral treaties, is that States enter into obligations or contracts with each other to achieve stated collective aims, which would not be possible in the absence of a formal international agreement. An international treaty is an exercise of sovereignty not a surrender of sovereignty. However, with the FCTC treaty there appears to be a ‘sharing’ of internal sovereignty, because its premise is to regulate internal affairs where compliance in one State has no bearing in another.

This is not to say that health issues do not extend beyond borders and cannot cause global risks – they can and do. ‘Given the cross-boundary effects of health threats, a State’s failure to identify and respond promptly to domestic health threats poses substantial risks to both its own citizens and other nations.’²⁸ This was evident most recently with the outbreak of SARS and, historically, with smallpox which had to be dealt with using the International Health Regulations. But the FCTC is not a set of international regulatory guidelines for States to follow; it is a legal treaty - the political rationale for which is that tobacco is a ‘global epidemic spread by the vector of advertising.’²⁹

There is an expectation associated with international law that it serves to regulate issues between and among nations. Yet, apart from regulatory guidance relating to the illicit trade in the product, duty free sales and tobacco advertising that crosses borders from one jurisdiction

²⁶ Ibid page 288

²⁷ Ibid pages 288 & 289

²⁸ First Do No Harm - chapter 5, The international health regulations – a new paradigm for global health governance? Lawrence Gostin.

²⁹ Various NGO publications

to another, the FCTC does not have any international elements which one might expect to find in an international treaty. For the most part it provides regulatory guidance on internal domestic issues which have no collective international interest; in contrast to, for example, an environment treaty providing domestic guidance where the acts of one State will impact directly the environment of another State. ‘For an international treaty, the FCTC has remarkably little to do with international relations, and primarily covers matters pertaining purely to domestic law.’³⁰

For these reasons, there is no global mechanism exactly like the FCTC in terms of reach and domestic implications and, consequently, the international law precedents that it establishes are especially significant. There are few processes that open such wide doors into a State’s approach to health regulation - from advertising and media to information disclosure to labelling language to product standards. It is not surprising that health advocates for other sectors such as alcohol are now using the FCTC as a model for further activism.³¹

The FCTC represents a unique intersection between governments and NGOs; idealised health goals and commercial/fiscal realities; political symbolism and pragmatic stipulations; and globalised policy and local actions. What is more, it has all taken place under a fairly new rhetorical rubicund centred on the protection of human rights and universal access to health yet denying health related rights to those that use the product. Perhaps it was because of the idealism associated with refining such a bold new international legal instrument that officials missed the one vital element for which the FCTC should have provided a regulatory framework – reducing the harm of the product. And it may explain why there is likely to be continued resistance to efforts to rectify this situation as the FCTC process continues to unfold.

This essay will discuss the public health aims of the WHO (and its supporters) in relation to the development of the FCTC by examining generally the travaux preparatoires for the treaty during the FCTC negotiations and how the Convention took shape in order to explain why the substantive issue of harm reduction was ignored, and that this was due in part to a flawed

³⁰ Gregory F. Jacob – “Without Reservation” Chicago Journal of International Law Vol 5 No 1 Summer 2004

³¹ The Global Alcohol Policy Alliance “The Globe” “The uniqueness of the FCTC Alcohol Advocacy - Lessons to be learned from tobacco”

http://www.ias.org.uk/resources/publications/theglobe/globe0503_0601/gl05030601_p14.html

treaty making process. It was also make the case that harm reduction and the creation of a regulatory framework that allows consumers to make decisions based on documented risk over the range of nicotine delivery methods should be an integral component of the still evolving treaty process. If consumer health advocates and tobacco policy makers are, as they have stated, genuine in wanting to secure a right to health for everyone, then it is anomalous to premise all regulation on the highly improbable goal of complete cessation instead of a combination of cessation and the provision of the least risky options. The issue is immensely topical and the process to achieve such an outcome through yet-to-be-negotiated adjuncts to the treaty has already been established and negotiations are imminent. The FCTC itself already provides the legal framework for the inclusion of tobacco harm reduction - what is lacking is the political will to put the issue on the table.

Part 1 - The FCTC – Process, Precedent and Politics

A new kind of treaty?

Protecting consumers from themselves and their ill-advised decisions is a relatively new motivation for international policy making, notwithstanding the fact that the trend in the creation of international treaties evolved considerably over the last century. From the inception of the United Nations until the Sixties, treaties involving questions of rights and welfare were mostly viewed as a mechanism for dealing with issues with cross border implications³². The reason behind this was simple: with war and conflict part of the immediate policy landscape, there was a perceived need for greater structure around how the citizens of one country could be treated by another country. This was, after all, why the United Nations and its subsidiary organisations had been established in the first place. But, with the Sixties bringing about a rise in social consciousness and more organised social movements for change, so too came a demand for more welfare orientated international

³² Examples include: <http://www.who.int/hhr/readings/treaties/en/index.html> Convention (No. 105) on Abolition of Forced Labour (1957), Convention Relating to the Status of Refugees (1950), Geneva Convention Relative to the Protection of Civilian Persons in Time of War (1949), Geneva Convention Relative to the Treatment of Prisoners of War (1949), Geneva Convention for the Amelioration of the Condition of Wounded, Sick and Shipwrecked Members of Armed Forces at Sea (1949), Geneva Convention for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field (1949).

policy³³. Perhaps because of this, the last few decades of the last century saw a greater institutionalisation of the concept of ‘rights’ and elaboration of mechanisms to combat exploitation and discrimination.

Of course other treaties were developed in direct response to a perceived problem: nuclear proliferation³⁴; the growth in the international trade in narcotics³⁵; an increase in trans-national organised crime³⁶; the international movement of hazardous waste,³⁷ etc. These treaties generally seek to establish a systemic approach to the international ‘cooperation’ required to manage problems with well defined and serious cross border implications. Broadly speaking, such treaties tend towards general stipulations or recommendations on the domestic policy front e.g. developing a systemic plan to deal with an issue coupled with more defined international obligations such as information disclosure/reporting, cooperation between border control entities etc. The goals, for the most part, involve gaining legitimacy for a problem, forming an international response mechanism and establishing a framework within which more extensive and detailed policy development can occur. Product specific agreements have either focused on illicit products (arms, drugs) or understandably sensitive legitimate products (dangerous chemicals, etc). Again, such agreements recognise that the policies towards contentious issues adopted by a particular country can have a direct bearing on the management of that issue by another country. That is why product specific treaties generally deal with the monitoring and movement of goods so as to effect a degree of control and assurance for matters of safety, security and welfare.

Most treaties deal with State-to-State cooperation (either individually or collectively through the UN or a designated Conference of the Parties type structure). Thus, with respect to censure or a breach of obligations, action would be taken at the inter-governmental level. The

³³ Examples include: <http://www.who.int/hhr/readings/treaties/en/index.html> Convention on the Rights of Persons with Disabilities (2007), Maternity Protection Convention (No. 183, 2000), Convention (No. 182) on the Prohibition and Immediate Action for the Elimination of the Worst Forms of Child Labour (1999), Optional Protocol to the Convention on the Elimination of Discrimination against Women (1999), International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families (1990) Convention (No. 169) Concerning Indigenous and Tribal Peoples in Independent Countries (1989), Convention on the Rights of the Child (1989), Convention on the Elimination of All Forms of Discrimination Against Women (1979).

³⁴ <http://www.un.org/Depts/dda/WMD/treaty/>

³⁵ http://www.unodc.org/unodc/en/drug_and_crime_conventions.html,

³⁶ http://www.unodc.org/unodc/en/drug_and_crime_conventions.html

³⁷ <http://www.basel.int/>

legal frameworks created by the treaties are, on the whole, also pitched at a very high level. States must not be complicit in activities that they have agreed should not be countenanced. States are required to undertake certain defined actions in response to an activity, situation or occurrence that runs counter to the strictures of an agreement. States must undertake to put in place certain protective/peremptory mechanisms to avoid particular outcomes and undertake due diligence to know what is going on with respect to an activity/issue.

The FCTC has components of all the above treaties. Some of its constituent parts do deal with genuinely international issues such as the growth in the illicit trade in tobacco products and the issue of cross-border advertising. It is also designed to combat a high profile ‘welfare’ related problem that has garnered international attention: the consumption of a risky product that can kill people. It invokes existing UN language on rights although it takes it to a new level: in this instance not only in enshrining the right to health of all people, including smokers, but more specifically, the rights of non-smokers through protection from environmental tobacco smoke. Like many other treaties, it also contains elements of international cooperation: exchanging information; sharing best practices etc. Yet, despite containing elements of many existing treaties, the FCTC is an entirely different mechanism to anything that predates it.

The differences really come down to a matter of degree. For example, while tobacco use is clearly deemed problematic and antithetical to health goals by a large number of countries, it isn’t really an ‘international’ problem in that what one country does has a direct bearing on another, such would be the case in an environmental treaty such as the Framework Convention on Climate Change, where domestic actions in one country can directly impact another country. Indeed, arguably, cultural perceptions of smoking, the market profile for tobacco products and successful regulatory responses differ markedly between countries. Additionally, tobacco is a legitimately traded product in most countries around the world³⁸, and so, somewhat unusually, all of the FCTC stipulations relate to a (relatively) freely available product. The FCTC also gets down into the weeds of domestic policy with a degree of comprehensiveness that is remarkable. As such, it is much more of a functional regulatory handbook than most other treaties which are more conceptual or offer general guidelines in

³⁸ It is only banned in a province of Bhutan

their approach. ‘The FCTC bears less of a resemblance to a true framework convention than it does to the Napoleonic Code.’³⁹

Many of these differences are explicable. The FCTC is the first explicitly public health orientated treaty to be agreed under the UN system. It is also the first treaty to be negotiated under the auspices of the WHO⁴⁰, predominantly by health officials without experience of multi-lateral treaty negotiation and its unique processes and terminology; and with a high degree of involvement by civil society supporters. Not surprisingly, given this groundbreaking context for a negotiation, many of the conventions and precedents regarding treaty formation simply didn’t apply.

One of the author’s first observations of the negotiation at the third FCTC international negotiating session in November 2001 was the extent to which it appeared amateur in not following norms of treaty negotiation such as the diplomatic disciplines around bracketed text, the traditional use of ‘informal’ negotiating groups to enhance progress, or the way negotiating coalitions were structured. It was evident when considering the make up of delegations that most were comprised of health officials, scientists, and doctors; and while they may know a lot about tobacco and health they did not know much about the creation of policy or the creation of international law. This view is supported by Gregory Jacob from the United States negotiating team:

‘The object of a treaty negotiation is the *making of law*, and that is not something that public health ministers are necessarily particularly well equipped to do...the inexperience of so many of the delegates with the enterprise of treaty-making, coupled with the inexperience of the WHO itself, significantly exacerbated other problems inherent in the WHO negotiation structure...it was readily apparent almost from the outset that the negotiating process had become dysfunctional...’⁴¹

One of the most significant results of having so many inexperienced delegates was that this gave NGOs accredited to the WHO room to be highly regarded providers of advice to government delegations – often in areas that went beyond their substantive expertise. NGOs undoubtedly should have a role in providing advice to governments but during the Geneva negotiations it was often difficult to tell them apart from government delegates. ‘These tactics

³⁹ Gregory F. Jacob – “Without Reservation” Chicago Journal of International Law Vol 5 No 1 Summer 2004

⁴⁰ Article 19 of the WHO Constitution

⁴¹ Jacob

would not have been so disturbing if they had not had much of an effect, but the inexperience of many of the delegates rendered them ripe for capture by sophisticated NGOs.⁴² Unlike the tobacco industry, which did not really have its act together, (many of the companies didn't even have positions on the treaty until well into the process and struggled to work out how or if they should engage), the NGOs were a credible global force and went out and lobbied for what they wanted. In the context of this process they were, and still are, expert in crafting public affairs strategies and their achievement on this issue is likely to be a textbook case in the future. 'The NGOs complained vociferously about a supposed tobacco industry lobbying campaign aimed at sinking the Convention, but other than a couple of representatives of the duty-free lobby, the tobacco industry was nowhere to be found. By contrast, the NGOs, worked the halls masterfully...'⁴³ and the final FCTC gives a precedent setting role to civil society in implementing the FCTC as an institutional part of the process.

*"Emphasizing the special contribution of nongovernmental organizations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions, to tobacco control efforts nationally and internationally and the vital importance of their participation in national and international tobacco control efforts...[T]he participation of civil society is essential in achieving the objective of the Convention and its protocols."*⁴⁴

The tobacco industry, on the other hand, is specifically not to be consulted:

*"Recognizing the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts... [I]n 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."*⁴⁵

Compare this eventuality with the energy industry which is at the heart of deliberations surrounding the Framework Convention on Climate Change. The front cover of a recent edition of *The Economist* leads with: 'Cleaning up – a 15 page report on how business is

⁴² Jacob

⁴³ Jacob

⁴⁴ FCTC Preamble and Article 4.7

⁴⁵ FCTC Preamble and Article 5.3

tackling climate change'.⁴⁶ Not only does the article outline what business is doing it outlines where governments need to help – which is in stark contrast with the tobacco industry's relationship to its governing Convention.

Given the dynamic of the negotiation and the defined anti-tobacco prism through which all of the treaty issues were viewed, it is not surprising that the question of harm reduction was quickly put to one side. With unmitigated anti-tobacco sentiment being the central premise of the entire process, the incentive to delve into the subtleties of questions of relative harm was absent. And, with the tobacco industry successfully ring-fenced out of the proceedings there was no one to pursue the issue. The driving idealistic force behind the initiation of the FCTC, the whole structure of the negotiations, the principals involved in the delegations (both officials and NGOs) worked against any kind of intervention that might have challenged the 'all tobacco is equally evil' and 'quit or die' sentiment that pervaded the process.

Evolution of the FCTC

To put the final treaty agreement in context and examine what made the final cut and what did not, it is useful to compare the travaux preparatoires to see what appeared in the initial draft Chairs Text,⁴⁷ prepared by the Chair, the WHO and selected experts, and what was agreed following the multiple rounds of negotiations. The reason that such a comparison is helpful is that it demonstrates how far WHO member states moved on key issues and where the true points of contention lay, as well as insight into the influence of the views of powerful NGOs on the often inexperienced delegates taking part in the treaty development process.

The initial draft was almost exclusively phrased around commitments invoking the legally imperative word 'shall'. The significance of this should not be underestimated. States would have been bound to implement specific dictates contained in the Convention. But, the final text replaced most of the 'shalls' with the less imperative 'will' or the even more relaxed 'should.' Notably this change came about when more legal experts started joining delegations. The structure of the Japanese delegation, as referenced in an article by Mary

⁴⁶ June 2-8, 2007 edition

⁴⁷ http://www.who.int/gb/fctc/E/E_inb2.htm

Assunta and Simon Chapman of the School of Public Health, University of Sydney, Australia, was indicative of what was seen in a large number of delegations:

‘...the composition of the Japanese delegation also varied with the progress of the negotiations. At the first two INB sessions, Japan’s delegation consisted mainly of representatives from the Ministry of Health, Welfare and Labour and had no representation from the Ministry of Finance. However, by INB6 there were as many representatives from the Ministry of Finance as there were from the Ministry of Health...’⁴⁸

Jacob also comments on the make up of the delegations:

‘One of the phenomena produced by the predominance of health ministers at the INBs in Geneva, however, was that the U.S. was placed in the position of negotiating not with foreign states but rather with foreign health ministries – ministries that were not necessarily pursuing policies favoured by their home governments. It quickly became clear that many of the delegates had experienced frustration in the past in trying to persuade their home governments to adopt strong anti-tobacco measures. These delegates saw the FCTC as an opportunity to do an end-run-around their governments by inserting strong anti-tobacco measures into the Convention and then relying on international political pressure to force their governments to join it. Some of the delegates openly admitted their ulterior agendas, making plaintive appeals from the floor of the negotiations that strong language needed to be inserted into the treaty so that they could force the hand of their government back home. This dynamic was particularly apparent in the debate over the ‘no reservations’ clause. Surprisingly large numbers of delegates argued in favour of the provision on the grounds that if reservations were allowed, their own government would be likely to take some. I felt as though I had stepped into the Geneva edition of the Twilight Zone, as I watched the representatives of governments that apparently would have liked to take reservations to the Convention deliberately acting to deprive their governments of the opportunity to do so.’⁴⁹

Legal specialists and officials more familiar with treaty law began to populate delegations as the negotiations wore on. They were concerned at some of the sweeping changes being countenanced by health officials who were less familiar with the implications of signing up to legal commitments on a global scale. Due in large part to this changing dynamic and corresponding expressions of concern about the reach of the FCTC, the few ‘shalls’ that remain in the final text tend to be diluted by subsequent language: for example ‘shall

⁴⁸ <http://jech.bmj.com/cgi/content/full/60/9/751>

⁴⁹ Jacob

endeavour to’ or ‘shall, to the extent possible’ which leaves open an obvious degree of flexibility.

In terms of product and supply components of the FCTC, the initial Chair’s text bears little relation to the final version. Language on price and tax measures that would have seen a global ban on duty-free sales, a hike in taxes across the board and Parties compelled to adopt tax measures defined by the Conference of the Parties⁵⁰ was quickly diluted when a number of horrified treasury and finance officials realised that the WHO would have influence over the preciously held sovereign right of tax determination. Consequently, the final treaty acknowledges the link between prices and consumption and encourages parties to impose taxes and dictate prices accordingly.

‘Another novel feature of the Convention is the inclusion of a provision that addresses liability’.⁵¹ Article 19 of the FCTC sets international law precedents by recognising liability as an important part of comprehensive tobacco control and specifically encouraging the consideration of right of access to courts in other Parties’ jurisdictions, of affording one another assistance in civil and criminal proceedings, and encouraging the future Conference of the Parties to consider liability for future international attention.⁵²

The whole question of international trade in tobacco raises another interesting aspect of the Convention which changed markedly as negotiations wore on. Many countries wanted tobacco to be exempted from international trade law and for ‘health rights’ to be placed above ‘trade rights’ on the basis of protection from the tobacco industry and its imports, ‘...an appeal that almost seemed sympathetic until one realised that it was only the *foreign* tobacco industry they were crusading against, while they were busily propping up their domestic companies.’⁵³ There was also a provision that would have enabled countries to meet their advertising ban obligations by banning the imports of violators of the FCTC advertising ban in their own country. For example, a cigarette logo on a car racing in one country showing up on a TV in another country would enable that country to ban imports of cigarettes from the

⁵⁰ http://www.who.int/gb/fctc/E/E_inb2.htm a) b) and c) in the draft)

⁵¹ Forward to the FCTC in official WHO publication

⁵² FCTC Preamble and Article 19

⁵³ Jacob

first country. ‘Most proposals of this nature were ultimately beaten back, but the Convention does include a handful of provisions that were designed by their sponsors to aid them in trade litigation’.⁵⁴

The final version of the FCTC is significantly less than what was initially envisaged - but not that it lacks impact. Indeed, it is still a comprehensive document. It mandates an advertising ban and the cessation of sponsorship and other promotional activities subject only to constitutional constraints. It promotes large, visual and rotating health warnings on tobacco products and requires the banning of descriptors such as ‘light’ and ‘mild’. It draws a link between environmental tobacco smoke and disease and recommends comprehensive smoking bans. It requires countries to consider pricing and tax under the overarching consideration that high prices discourage tobacco use (but does not recognise that without balance it can also increase smuggling). It contains comprehensive requirements on the disclosure of information on the part of the tobacco industry. It requires tobacco regulatory authorities to be established or existing authorities to have their mandate expanded to accommodate the requirements of the convention. It sets out multiple initiatives for consumer education and outreach to disseminate anti-smoking messages more broadly. It establishes numerous reporting requirements and cooperation measures to link up Parties.

Given then the differences between what was contained in the first FCTC draft and what was agreed, it is interesting to look at how the treaty is being implemented in various WHO member states. However, it is important to note that the FCTC is still relatively new and, in many cases, implementation is still a work in progress. Furthermore, the Conference of the Parties has only met once (30 June – 7 July 2007 is the second meeting) and has yet to analyse and critique the ratification efforts of the Parties. It is certainly the case that there is a wide divergence of tobacco control policies among WHO member states. Yet the FCTC is being felt all around the world. Public smoking bans pegged to the FCTC are increasingly common. A public smoking ban came into effect in Ireland in March 2004⁵⁵ and is due to come into force in the UK on 1 July 2007.⁵⁶ In Australia legislation came into force on 1

⁵⁴ Jacob and FCTC Article 13.7

⁵⁵ Public Health (Tobacco) (Amendment) Act 2004 - <http://oireachtas.ie/documents/bills28/acts/2004/A0604.pdf>

⁵⁶ Health Bill 69, <http://www.publications.parliament.uk/pa/cm200506/cmbills/069/06069.i-v>.

March 2006⁵⁷ requiring that all tobacco products imported and manufactured for retail in Australia are to be printed with new health warning labels. The new warnings provide smokers with information on an expanded range of health effects. In the case of cigarette packs, graphic health warnings will occupy 30% of the front and 90% of the back of pack. Display of tobacco brands and communication of any sort to consumers is being curtailed in many markets. In Iceland a ban on point of sale advertising took effect force on 30 June 2006⁵⁸, and in the UK an advertising ban that had come into force on 14 February 2003 was fully implemented on 31 July, 2005 when sponsorship was outlawed.⁵⁹

There are 147 FCTC Parties and the level of domestic compliance is significant, given as stated earlier that actions in one country have little impact on actions in another that warrants an international approach. Article 2.7 of the UN Charter, under which the WHO as a UN specialised agency is established, states ‘nothing contained in the Charter shall authorise the United Nations to intervene in matters which are essentially within the domestic jurisdiction of any state...’ and yet the WHO FCTC contains articles regulating areas usually outside the domain of international law and clearly in the domain of the sovereign right of States such as taxation, liability, communication relating to a legal consumer product, and the role of NGOs in domestic implementation of policy.

The FCTC as a 'perfect storm' in terms of policy generation

There has been a great deal of analysis aimed at seeking to define exactly why the FCTC was able to gain the momentum and domestic impact that it did. While there is contention as to which factors were most significant, there is little contention of the fact that it was a fairly unique combination of personalities, events and trends that created the necessary drive. It took a tobacco industry that had conducted itself in a highly questionable and arrogant manner for many years, the right personalities in the global policy environment to act as a catalyst, powerful activism on the part of well funded and organised NGOs, major precedents such as

⁵⁷ Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004 Statutory Rules 2004 No. 264 http://tobacco.health.usyd.edu.au/site/supersite/resources/pdfs/TPA_SR_2_64.pdf

⁵⁸ Tobacco Control Act 6/2002 <http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/689>

⁵⁹ The Tobacco Advertising and Promotion Act 2002 <http://www.opsi.gov.uk/ACTS/acts2002/20020036.htm>

the U.S. Master-Settlement Agreement (MSA)⁶⁰, the expansion of global policy opportunities afforded by globalisation trends, a string of incentives (both carrots and sticks) to developing countries economically reliable on tobacco, a series of international world conferences against tobacco, as well as funding to the WHO budget from a pharmaceutical industry that stood to gain commercially through global legitimacy of its tobacco cessation and nicotine replacement products.

There is little doubt in the minds of most tobacco control commentators that Gro Harlem Brundtland, former Prime Minister of Norway and Director-General of the WHO during the FCTC negotiations was a major catalyst in the development of the FCTC. As the Global Health and Environment Monitor writes in the same vein as many others: ‘The process accelerated in 1998 when Dr. Gro Harlem Brundtland became the director-general of WHO. Brundtland immediately created a cabinet-level post on tobacco and demanded that work on the FCTC proceed.’⁶¹ Dr Derek Yach, former head of the TFI was candid about Brundtland’s role: ‘The most important thing was having Brundtland come in and think very deeply during her transitional period about the kind of problems that would attract international support to the agency and would allow her to do business in new ways. She chose malaria and tobacco as her pathfinder projects, and I was privileged to head the Tobacco Free Initiative.’⁶² The leadership exhibited by Brundtland was instrumental in getting the FCTC off the ground – she had the credibility, the credentials⁶³ and the political smarts to create support, generate action and present the process as something akin to a fait accompli. In fighting off questions as to whether an international treaty was necessary for a predominately domestic issue such as tobacco control. Dr Brundtland stated ‘Tobacco control cannot succeed solely through the efforts of individual governments, national NGOs and media advocates, we need an international response to an international problem. I believe that response will be well encapsulated in the development of Framework Convention’.⁶⁴

⁶⁰ www.in.gov/attorneygeneral/legal/litigation/msa.pdf. The MSA was the largest civil settlement in United States history arising out of many separate legal actions brought by various US States against the tobacco industry for Medicare costs associated with smoking-related diseases. The agreement was originally negotiated between the four largest tobacco companies and 46 US States and 6 US Territories. It exempted the companies from tort liability from state governments and settled the lawsuit in exchange for a combination of yearly payments to the states and voluntary restrictions on advertising and marketing of tobacco products.

⁶¹ <http://www.ceche.org/mol/Winter-05/jump-1.html>)

⁶² <http://multinationalmonitor.org/mm2005/052005/interview-yach.html>)

⁶³ http://womenshistory.about.com/od/brundtland/Gro_Harlem_Brundtland.htm)

⁶⁴ Seminar on Tobacco Industry Disclosures, WHO, Geneva, 20 October 1998, Technical briefing series

The MSA created a new and lucrative source of tobacco control revenue for States and civil society groups involved in anti-smoking efforts. Given that anti-tobacco NGOs were already well established as the ‘preferred providers’ of information, analysis and initiatives against tobacco, the funding served to exponentially accelerate and expand the level of activity.

‘Only governments can propose and enact tobacco control laws. Only NGOs can mobilise political support and pressure governments to take action, when necessary. Tobacco control advocates can give government officials vital information. NGOs can also help them write the most effective laws and regulations. In exchange, government officials can give NGOs vital political intelligence to help them advocate effectively.’⁶⁵

Further, as many of the NGOs active in the U.S. were international in terms of having subsidiaries elsewhere or being affiliated to an organisation based outside the U.S., the effect was a global one. The California example is instructive of the type of anti-smoking activities that were generated. In California, under the terms of the MSA, a foundation funded by (but not in any other way associated with) the tobacco industry was established to:

‘Carry out a nationwide, sustained advertising and education program to counter youth tobacco use and educate consumers about the cause and prevention of diseases associated with tobacco use. Develop, disseminate and test the effectiveness of counter advertising campaigns. Commission studies, fund research and publish reports on factors that influence youth smoking and substance abuse. Track and monitor youth smoking and substance abuse with a focus on reasons for increases or failures to decrease tobacco and substance use rates. Create an industry-funded \$1.45 billion national public education fund for tobacco control. The fund is established to carry out a nationwide sustained advertising and education program to counter youth tobacco use and educate consumers about tobacco-related diseases’⁶⁶

What this did was to create a well funded, highly organised and legitimate groundswell of anti-tobacco initiatives. Not surprisingly, the impact was global. Campaigns and information gathered in the U.S. were exported elsewhere to form the basis of related anti-tobacco efforts. The money flowing into anti-tobacco NGOs helped to kick-start new high profile campaign and awareness/fundraising around the world. Invigorated by the MSA and such an

⁶⁵ www.paho.org/English/AD/SDE/RA/Guide2_MovementBuilding.pdf).

⁶⁶ <http://ag.ca.gov/tobacco/resources/msasumm.php> Requires the industry each year for ten years to pay \$25 million to fund a charitable foundation which will support the study of programs to reduce teen smoking and substance abuse and the prevention of diseases associated with tobacco use.

unequivocal statement regarding the culpability of the tobacco industry, NGOs seized the opportunity to expand, bolster their relationship with governments and health organisations, create programs to exploit new funding channels and globalise the results. A very well coordinated and highly motivated group of activists, with close links to government agencies was the result.

Another impact of the MSA was the messaging that it promulgated. Putting aside the financial stipulations of the verdict, the judgement clearly had components that influenced the FCTC.⁶⁷ The settlement stipulated in detail a whole raft of restrictions and rules to which the tobacco industry must comply. In considerable detail the verdict establishes the parameters within which the industry can operate in terms of advertising, industry associated access to product etc. Further, the psychological impact was significant. If the U.S., one of the global leaders in tobacco production and export and a notorious political supporter of the tobacco industry, could hand down an extraordinarily punitive and comprehensive judgement against the industry, just imagine what the rest of the world could do.

Another important factor in the rise of the FCTC was the trend towards globalisation and the highly organised movement against it. On the one hand, globalisation meant that information and awareness was becoming increasingly internationalised and civil society groups were becoming better linked up and coordinated – just as was happening with businesses. And, through agreements such as the WTO Uruguay Round outcome, both States and civil society groups were getting more used to (if not comfortable with) the presence of a global framework governing processes like international commerce, corporate rights etc. On the other hand the backlash to the expanding reach of multinationals and the more defined rights of commercial entities was pronounced and was generating aggressive push back. This created a slightly schizophrenic approach to tobacco health policy. On the one hand, many of the groups most vocal in pushing for the FCTC were as much anti-corporate and corporate ‘abuse’ focused as anti-tobacco per se.

This was well articulated by one of the most active FCTC NGOs, the Network of Accountability of Tobacco Trans nationals (NATT) an affiliate of Corporate Accountability International. NATT is ‘made up of more than 100 organisations in 50 countries, including

⁶⁷ <http://academic.udayton.edu/health/syllabi/tobacco/summary.htm>

consumer, environmental, fair trade, human rights, faith-based and corporate accountability organisations'.⁶⁸ On its website NATT claims:

‘Corporate Accountability International and NATT played a vital role in mobilising global support, especially in developing countries, for the adoption of the global tobacco treaty by the World Health Assembly in May 2003. NATT members also pushed for effective advertising and promotion limits and measures that restrict tobacco industry interference in public health policy. Those curbs on the industry have been written into the treaty.’

The irony is that anti-globalisation protest groups were essentially the most aggressive advocates for a global response to the tobacco issue. As Tikki Pang and Emmanuel Guindon (of the WHO) wrote in a 2004 article titled *Globalization and risks to health*:

‘As borders disappear, people and goods are increasingly free to move, creating new challenges to global health. These cannot be met by national governments alone but must be dealt with instead by international organizations and agreements...and although many NGOs decry the negative effects of increasing globalization, they have also clearly benefited from it to improve healthcare delivery and health policy in many developing countries. A recent key contribution of the global NGO movement lies with the adoption of the FCTC. NGOs had an essential and vital role at the local, national and international levels in all development phases of the FCTC, and their contribution continues as they actively work with countries in the FCTC ratification process.’⁶⁹

Certain developing countries were initially sceptical of the FCTC process. Although wanting to deal with the problems associated with tobacco consumption, several pointed out that significant foreign exchange dollars were generated by tobacco production. They were worried about having the economic carpet pulled out from underneath such an important agricultural sector. The response to this was two-fold. On the one hand, WHO officials began talking up the prospect of having a ‘global fund’ to mitigate against the consequences of transitioning out of tobacco production. Early drafts of the FCTC had very specific language on this fund, which was lauded as the mechanism through which everyone could draw on resources to deal with the problem. It wasn’t entirely clear where the money would come from, but with the MSA fresh in the collective consciousness of WHO members there was a general belief that somehow, developed country tobacco exporters and/or tobacco

⁶⁸ <http://www.stopcorporateabuse.org/cms/page1144.cfm>

⁶⁹ <http://www.nature.com/embor/journal/v5/n1s/full/7400226.html>

companies would pay. Many countries came up with options for funding with text proposed by Brazil being broadly indicative of the general trend:

‘ The Parties acknowledge that the developing countries, particularly those whose national economies depend on the tobacco industry, and on tobacco growing in particular, need support in order to diversify their crops, adopting other feasible options through an appropriate financing mechanism.’⁷⁰

However, co-operation between the WHO and other UN affiliated or related institutions were making it harder for countries to develop their tobacco sectors.⁷¹ The World Bank was especially active in involving itself in tobacco control activity through an extensive range of programmes and projects and would not fund tobacco related projects or projects with direct links to tobacco (e.g. Irrigation).⁷² Dr Judith Mackay led the World Bank’s push behind tobacco control and recently *Time* magazine named her one of the ‘most influential people in the world’ in recognition of her role as a leading campaigner for stricter tobacco control measures and vigilant critic of tobacco industry practices...and a key player in the development of the landmark WHO Framework Convention on Tobacco Control, one of the most widely and rapidly endorsed treaties in United Nations’ history.’⁷³

The International Monetary Fund (IMF) adopted anti-tobacco language and the Food and Agriculture Organisation (FAO) also developed an anti-tobacco platform. What this meant was that the scope for developing countries to develop their tobacco industries was limited at the same time as funding for transitioning away from tobacco was being advocated. As it turned out the actual money did not materialise although by the time that the idea of global fund was put aside, most developing countries were already well integrated into the FCTC process and being carried along on a tide of multilateral activism against tobacco. Just as important were efforts by the WHO to integrate tobacco control into the spectrum of health

⁷⁰ www.who.int/gb/fctc/PDF/inb1/e1inbcp13.pdf.

⁷¹ www.who.int/entity/tobacco/media/en/unreportII.pdf “ The World Bank’s work on tobacco control is being conducted in close partnership with WHO’s Tobacco Free Initiative, and with other organizations, including the US Centers for Disease Control and Prevention Office of Smoking and Health, the IMF, the UN Foundation, FAO and other organizations.

⁷² <http://www1.worldbank.org/tobacco/presentation.asp>: The World Bank's role in the global partnership to reduce harm from tobacco use. Talk given by Joy de Beyer at World Health Assembly, Geneva, May 2000.

⁷³ WHO website

programs making it harder for developing countries to pick and choose programs in which they might want to be involved.⁷⁴

In addition to all the ‘actors’ taking part in the production of the FCTC, there were additional stages on which all these actors could come together to discuss, debate and showcase what was happening to advance the tobacco control agenda. Perhaps the largest and most well funded of these conferences is the World Conference on Tobacco or Health (WCOTOH)⁷⁵, which every three years since 1967 has largely driven the international tobacco control debate. The main objectives of the WCOTOH are to exchange information and to stimulate action to promote tobacco control regulation. The 12th WCOTOH held in Finland in 2003 was attended by over 3,000 delegates and ran with the theme of *Global Action for a Tobacco Free Future*. Its declaration preamble congratulated the WHO member states for leadership in adopting the FCTC and NGOs for their role in advocating for the FCTC. ‘The magnitude of the epidemic requires a proportionate response’ it said, and called on governments to ratify the FCTC by January 2005 and to involve civil society in the process. In addition it called on all governments to contribute resources and funding proportionate to their GDP for the implementation and monitoring of the FCTC, and for non-governmental and philanthropic organisations to provide substantive contributions.⁷⁶ As it turned out, it was indeed other organisations that had provided a large chunk of the funding for the FCTC and conferences such as WCOTOH to take place. The pharmaceutical company Pfizer was the main sponsor of the 12th WCOTOH conference⁷⁷ and it was made clear throughout the week-long meeting that the financial viability of the conference was due in no small part of Pfizer. Pfizer also ran a daily column in the conference news letter featuring a ‘quitting diary’ and noting that cessation products make quitting very much easier. At the 12th WCOTOH there were numerous bright and glossy stands focusing on cessation products and the wider tobacco control agenda, including analysis of the success of regulatory measures.⁷⁸ The pharmaceutical company Glaxco Smith Kline (GSK) in particular was clearly attempting to

⁷⁴ <http://www.who.int/mediacentre/factsheets/fs172/en/index.html> WHO's Non-communicable Diseases and Mental Health cluster has created a new framework for assisting countries to reorganize their health care for more effective and efficient prevention and management of chronic conditions.

⁷⁵ It was the first gathering of the world’s leading scientists devoted entirely to smoking and health. Dr. Luther Terry was the chairman. He was the U.S. Surgeon General who issued the historic 1964 report entitled ‘Smoking and Health’.

⁷⁶ Declaration to WCOTOH 2003

⁷⁷ Also sponsored 13th WCOTOH in Washington in July 2006

⁷⁸ The author attended the conference and took photographs

list itself as the ‘partner of choice’ for tobacco control. At the GSK ‘Science against Smoking’ exhibition stand, GSK staff handed out a CD-Rom containing several hundred PowerPoint slides called ‘The Tobacco Trap’.⁷⁹ The pharmaceutical company Novartis was also a sponsor but appeared to be present only to directly promote tobacco cessation products. Judging by the creation of high tech and very smart stands including a huge ‘*Welcome to Nicorette*’ billboard utilising all the banned Marlboro man imagery. It was evident that the pharmaceutical industry was investing and supporting tobacco control policies financially. One of the recurrent messages of the WCOTOH was to ‘change regulation to make it less restrictive on pharmaceuticals so as to enable it to compete with tobacco companies.’

It was clear that there were not going to be elements of reducing the harm of the product in the FCTC while there was funding for inclusion of regulation to enable the supply of other products to help smokers quit – even if those products use nicotine (derived from tobacco) to have their effect. The factors at play were profound – the main message of the NGOs, which had a formal institutionalised role in the implementation of the treaty, was to encourage only ‘quit or die’ themes; the WHO wanted a speedy success and so endorsed ‘tobacco deadly in any form’ theme. There was funding of the process from a pharmaceutical industry that wanted its products endorsed in the treaty; a government sector that presented as ill-informed or found tobacco too politically sensitive to discuss; a tobacco industry that appeared ‘shell-shocked’ and was saying nothing. It was hardly surprising then to end up with a tobacco control treaty that endorses the use of pharmaceutically produced tobacco cessation products and ignores the crucial issue of reducing tobacco product harm, but instead to end up with legal endorsement of pharmaceutical products in the treaty:

‘Towards this end, each Party shall endeavour to collaborate with other Parties to facilitate accessibility and affordability for treatment of tobacco dependence including pharmaceutical products pursuant to Article 22...’⁸⁰

⁷⁹ Contains policy advice on tobacco control policy measures including - regulations to reduce public and workplace smoking, increased taxation, bans on advertising and promotion, health warnings on packaging, deregulation of nicotine replacement products, reducing the supply of tobacco. States GlaxoSmithKline is committed to improving world health by working with government, professional and voluntary organizations and individuals to develop an evidence-based tobacco control policy.

⁸⁰ FCTC Article 14.2(d)

Part 2 – Some human rights are more important than others

Harm reduction - a human right?

There are around 1.3 billion smokers in the world. Under a scenario of stunningly successful implementation of global tobacco control programs generated by the FCTC, there will still be according to the WHO about 900 million to 1 billion smokers in the world by 2030. They could still be consuming the current range of tobacco products, or could be consuming other forms of tobacco and nicotine in substantially safer forms that could dramatically reduce their risks for premature death and disease.

This scenario would only be possible if there was a clear regulatory framework for establishing the potential risks throughout the range of tobacco and nicotine delivery products based on sound science – a risk continuum that was clearly communicated to consumers enabling them to make informed choices in determining their health priorities. One might argue that to know this information is a basic human right, and at the very least a right in relation to the human right to health. When the FCTC preamble recalls the International Covenant on Economic, Social and Cultural Rights⁸¹ which provides for ‘the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’, and the preamble to the WHO Constitution, which states that ‘the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being...’ did it really mean to deny rights to smokers by omitting the whole issue of harm reduction? Or, put another way, the pursuit and proposed regulatory treatment of reduced risk products?

While it is the nicotine in tobacco that causes the dependence it is not necessarily what causes the harm.⁸² The harm from tobacco use generally comes from the smoke. Epidemiological evidence correlates a reduction in risk with a reduction in exposure to tobacco smoke. Therefore, if tobacco smoke exposure could be reduced or the toxins in tobacco smoke reduced it follows that there could be a reduction in harm. Several different approaches to reducing the harm in conventional cigarettes exist, but predominantly focus on either the general reduction of all tobacco smoke that enters the mouth and therefore exposure to the

⁸¹ Article 12 of the adopted by the United Nations General Assembly on 16 December 1966,

⁸² Nicotine is naturally occurring in the tobacco leaf. Different types of tobacco plant, different soils, different curing techniques and different blends all contribute to different nicotine levels.

lungs and reduction of specific toxicants in cigarette smoke. The measurement for general reduction is currently determined by International Standards Organisation (ISO) test methodology which measures exposure by using smoking machines – even tobacco companies agree that this method of measurement is unsatisfactory⁸³ due to human smoking behaviour which can significantly distort the machine readings and therefore any reliability on reduced yields.⁸⁴ For specific toxin reductions there is no generally accepted or established methodology for measuring exposure correlated against risk. Research needs to be undertaken to make inroads into these areas. It sounds simple enough but ‘tobacco science is not rocket science - it’s harder!’⁸⁵

In general terms a harm reduction policy or approach seeks pragmatic rather than absolutist solutions: e.g.: free condoms, air bags, speed limiters, needle exchange - the right to make a choice based on relative risk. According to Robert Wallace in his Institute of Medicine testimony to the US House of Representatives (2003) ‘Tobacco harm reduction refers to decreasing the burden of death and disease without completely eliminating nicotine and tobacco use.’⁸⁶ Leading tobacco control advocates Nigel Gray and Jack Henningfield said in *The Lancet* in September 2006 that: ‘...the term harm reduction can be applied to methods for reducing toxins in tobacco smoke by setting upper limits for them, to programmes promoting the conversion of continuing smokers to smokeless tobacco, or the long-term complete substitution of nicotine as replacement therapy for tobacco.’⁸⁷

Imagine that smoking could be compared to a disease like AIDS. In an ideal world (and within the paradigm that most countries are presently operating) people would be persuaded through various means – publicity, bans on risky behaviours such as sex with multiple partners appearing in films/media etc - to simply abstain from behaviours that might make them vulnerable. But, if people understand the risks and, despite all the social conditioning, still choose to indulge in risky behaviour, should they not have information about minimising the risk – i.e. safe sex and using condoms. The debate is interesting because it cuts to the

⁸³ BAT position on product guideline www.bat.com

⁸⁴ US NCI Monograph 13 etc.

⁸⁵ Personal conversation with Dr David O’Reilly, BAT

⁸⁶ Reference IOM

⁸⁷ Nigel Gray and Jack Henningfield, *The Lancet* (Sept 2006).

heart of agreements about social engineering: should people be protected from themselves by having no choice or should people protect themselves by making relatively safer choices?

At the 12th WCOTOH, leading tobacco control advocate and WHO consultant, Jack Henningfield asked in a presentation⁸⁸ whether, if it were possible to make a tobacco product less toxic and addictive through regulation could this make a difference? In comparing risks of known risky things he said with bullets there is the old fashioned kind and there is the armour penetrating variety; with guns there are single barrel and there are semi-automatic; with drugs there is cocaine and there is crack, with nicotine there is nicotine replacement therapy and there are cigarettes. He also said that there is a big difference between a bullet that is thrown to whether is it shot, referring to the variation in the speed of the delivery of nicotine through the range of nicotine delivery methods such as conventional cigarettes, cigars, smokeless tobacco, nicotine replacement therapies, nicotine chewing gum, lozenges etc. Others share his view:

‘There is little doubt that the cigarette could have been, and can be, made somewhat less dangerous. There is no doubt that it cannot be made safe and that, in the long term, it should be replaced as the major form of nicotine dose by tobacco-free products that deliver a similar or lesser ‘fix’ than the cigarette. Products very low in toxicity will be needed to prevent possible net adverse health consequences arising from increased use of any product that offers only modest risk reduction to individuals.’⁸⁹

If it were possible to produce a less harmful way of delivering nicotine to people than via cigarettes, should it be permitted and should consumers be informed about the existence? If it is permitted - how should it be communicated to consumers?⁹⁰ In putting reduced risk products on the market should manufacturers be required to make claims about the products or should governments set standards that manufacturers must meet? In establishing a risk continuum for tobacco products (cigarettes, cigars and smokeless tobacco) should regulators be including all other forms of nicotine delivery such as lozenges, nicotine patches, tablets, chewing gums, lozenges etc. as after all they are derived from tobacco? Would consumers not be advantaged by having a known a risk continuum of all tobacco (or derivative) products and having them all displayed alongside each other where they are for sale so as to enable

⁸⁸ Jack E Henningfield, Plenary Presentation: *Tobacco addiction: control by product regulation*

⁸⁹ <http://annonc.oxfordjournals.org/cgi/content/full/14/3/353> “More on the regulation of tobacco smoke: how we got here and where next” N.Gray and L. T. Kozlowski”

⁹⁰ Especially in a time when communication, advertising and marketing of tobacco is all but banned and discussion about a Protocol to the FCTC on banning cross-border advertising is about to begin.

informed choices along the risk range? These are the questions regulators should be asking and the FCTC as an existing international legal mechanism for collaborative tobacco control should be examining.

Sweden is the only country in the western world that has reached the WHO goal of reducing the percentage of smokers in the adult population to below 20%. It has Europe's highest consumption of smokeless tobacco but Europe's lowest cigarette consumption, lowest lung cancer mortality rate, lowest percentage of smoking related deaths among developed countries, among the lowest oral cancer mortality rate in Europe⁹¹. How has this been possible? Sweden has for hundreds of years used a tobacco product known as Swedish-style snus. It is comprised of finely ground heat pasteurised tobacco in a mini tea-bag like sachet that is placed into the mouth between the gum and lip and which delivers nicotine and flavour to the consumer without any smoke. In 2002, the Tobacco Advisory Group of the UK Royal College of Physicians said that 'Swedish-style snus is of the order of 10-10,000 times less hazardous than smoking, depending on the product.'⁹² In 2005 leading tobacco control activist and former president of the WHO's IARC, Dr Nigel Gray stated in *The Lancet*: 'So it is possible (however, reluctantly) to agree with BAT and Swedish Match that snus is a harm reduction product, but only when compared with a cigarette'.⁹³

Despite these and many other significant statements by leading medical and scientific bodies, the FCTC and the current development of tobacco product guidelines to support its implementation does not address the relative reduction in risk of Swedish-style snus. What is more is that Parties to the treaty therefore do not recognise it. Swedish-style snus is banned in the EU (apart from Sweden) and many other parts of the world. Outside of Sweden and of medical and scientific circles the product is barely known, due to restrictions on communication, which many doctors and scientists claim is a travesty given the relative lower risk of a product that still delivers nicotine but without the smoke – beneficial to both the smoker and those around the smoker that do not have to be exposed to with tobacco smoke.

⁹¹ Historical Supplement to presentation by Professor Brad Rodu, Department of Medicine, Endowed Chair, Tobacco Harm Reduction Research, University of Louisville, USA – New York May 2007

⁹² Tobacco Advisory Group, UK Royal College of Physicians, 2002

⁹³ Nigel Gray, *The Lancet* 2005 'Mixed Feelings on Snus'.

Article 8 of the 2001/37 EU Tobacco Product Directive states that ‘Member States shall prohibit the placing on the market of tobacco for oral use....’ Tobacco for oral use defined as ‘all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or particulate form or in any combination of these forms – particularly those presented in sachet portions or porous sachets – or in a form resembling a food product’. This is despite EU Directive review (article 11 review) which obliges the Commission to pay heed to ‘tobacco products which may have the potential to reduce harm’. There are calls to lift the EU ban on smokeless tobacco from tobacco companies and tobacco control advocates alike. At the UK National Smoking Cessation Conference in June 2006, the UK Royal College of Physicians said: ‘Some manufacturers want to market smokeless tobacco as a ‘harm reduction’ option...they may find support for that in the public health community.’⁹⁴ And Action on Smoking & Health (ASH) said: ‘We would welcome a new report by an independent body into the possibility of lifting the ban on snus.’⁹⁵

But despite these and other similar statements, in the absence of any formalised regulatory framework in which to understand the tobacco product risk continuum – either in any national regulatory framework or international regulatory framework there is no progress – either in terms of removing the ban or in providing consumer information on snus. There is not even any consensus on what to do because the debate is so factionalised for all the same reasons that prevented tobacco harm reduction from being an element of the FCTC in the first place:

‘I would say there are two clear factions in the public health community, some people who believe that saying anything positive about smokeless tobacco subverts the efforts to get people off tobacco and off cigarettes in general; and I think there's another faction which thinks there are these differential risks and we need to be honest with the public about these differential risks.’⁹⁶

Despite the fact that a product such as Swedish-style snus is generally accepted to be up to ten thousand times safer than a cigarette and that safer cigarette technology is increasingly well advanced, the issue raises a political minefield.

⁹⁴ UK Royal College of Physicians

⁹⁵ Amanda Sandford Research Manager ASH.

⁹⁶ Mr. LYNN KOZLOWSKI (University of Buffalo, SUNY): It’s the FDA regulation of tobacco bill

‘...but the fact is that modern smokeless tobacco products are considerably less harmful than cigarettes. No one should start using any form of tobacco if they can avoid it. But for those who are already lifelong smokers unable to quit nicotine altogether, smokeless tobacco at least provides a far, far safer (albeit not completely risk-free) way of getting nicotine. Nicotine, while highly addictive, is among the least harmful elements of a cigarette. It is the burning and inhaling of the tobacco which exposes users to the most deadly dangers. Not convinced? Consider this: the risk of oral cancer from smokeless tobacco is lower -- yes -- lower than the risk of oral cancer from smoking cigarettes. And using smokeless comes with virtually none of the other health risks associated with burning and inhaling tobacco from a cigarette. Public policies that ignore these facts undermine public health. Unfounded, unscientific pronouncements that lump all tobacco products and their risks together ultimately undermine the basic purpose of tobacco-regulatory policies. So instead of giving smokers tools to quit, the bill⁹⁷ hinders innovative approaches.’⁹⁸

Politically, ignoring the question of harm reduction is explicable and pragmatic. The momentum to introduce tough and sometimes controversial regulatory changes on the basis that people must be protected from their own decisions is doubtless diminished if shades of grey are integrated into negative assessments of the product options. “Smoking kills” is one thing but “some tobacco products are much worse than others” hardly galvanises attention in the same manner. Yet, where does that leave the consumer in terms of rights? Are there opportunities to remedy this situation by including tobacco product harm reduction in future guidelines and protocols to the FCTC?

The lost opportunity for health gains

It is not possible at this point in human health history despite years of debate in various pockets the world over to know the relative risks of one tobacco product or nicotine delivery product over another in any reliable way – including both tobacco and pharmaceutical nicotine products. There are lots of views and no doubt there always will be, but what is most concerning is that when the opportunity presented itself internationally to at least set a course to understanding the risks associated with tobacco and nicotine use and of achieving some international health consensus on a way forward – it was ignored.

⁹⁷ ‘S. 625: A bill to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products’

⁹⁸ http://www.acsh.org/healthissues/newsID.1531/healthissue_detail.asp ‘The Unintended Consequences of Tobacco Laws’

Given that the whole self-professed point of the FCTC was to protect health, it might seem anomalous that the relative risk of tobacco products and ways in which the FCTC might encourage a move towards reduced risk products barely entered into the debate. Politically this was understandable even if practically it represented a huge lost opportunity. From a political perspective, governments, international health bureaucrats and NGOs were determined to portray all tobacco products as one large collective evil to bolster the sense of urgency and outrage that was fuelling the FCTC. During the FCTC process experts testified that the only way to reduce tobacco consumption was to ‘denormalise’ all tobacco and contended that drawing distinctions between products would simply confuse the issue and provide opportunities for the tobacco industry.⁹⁹ It was also noted that no tobacco product could be proven to be absolutely safe and therefore complete cessation was the only truly effective way to protect people. A few lone voices asked questions such as whether consumers should have the right to make consumption choices based around relative risk and whether officials could, in good conscience, deprive them of the ability or opportunity to do so but they failed to gain traction. The WHO has subsequently paid lip service to the harm reduction debate¹⁰⁰. Harm reduction was sidelined.

Being able to have the right to make a choice based on relative risk is one thing; knowing what those relative risks are is another thing indeed. Both areas lack information. Where choices do exist consumers are prevented from getting access to such products. And where research is required to address the need to develop sound science around knowing how to measure the relative risks – it is not being done. There is currently no internationally agreed method for measuring or knowing the relative risk of one tobacco product compared with another one. Given the vitality of knowing or putting in place research to attempt to establish such information, it would have been a useful policy element to include in an international health treaty devoted to tobacco. Even if the WHO and its members driven by NGOs on a crusade to rid the world of tobacco were not going to countenance the inclusion of establishment of an international framework for risk reduction, it was not going to let anyone else do any research or have the debate either. It would always be problematic for the tobacco industry to gain acceptance for its own research as it would have credibility issues with no-one believing it, but government policies emerging globally on the back of the FCTC was (is)

⁹⁹ http://www.who.int/tobacco/fctc/conferences/oslo_final/en/print.html1.

¹⁰⁰ http://www.who.int/tobacco/communications/events/tob_harm_reduction/en/index.html

creating a policy vacuum effectively silencing the debate. Currently in most parts of the world, scientists are banned from receiving public or foundation funds for tobacco research if they accept funding directly or indirectly from the tobacco industry; all forms of advertising and marketing-including future messages about possibly reduced harm effects of new products are banned; and the tobacco industry is restricted from interaction with the public health scientists through policies related to conference participation and journal submissions. And while the WHO perpetuates the ‘tobacco in any guise is harmful’ message¹⁰¹ the development of a safe or safer tobacco product research is doomed to fail.

The almost entirely neglected question of tobacco harm reduction policy is still sitting in something of a policy vacuum. Many governments are so invested in the well rehearsed arguments against tobacco in any form that introducing qualifications into the regulatory picture is viewed as politically untenable. Further, few governments want to countenance opening up a potential door for the commercial exploitation of any tobacco products – even ones that are likely to be less risky to consumers. So, the vast majority of WHO members think that cessation and complete denormalisation of all tobacco is the easiest and safest regulatory approach. But this view is starting to be challenged by significant commentators in the tobacco control community. Known as the ‘architect of the FCTC’, Dr Derek Yach, former head of the WHO Tobacco Free Initiative in a recent interview said:

‘...In 20 years, if we are lucky, only 20% of the world’s population will still be smokers – equivalent to 1.3 billion smokers. And what is to be done with them? What is crucial here is getting them to use less harmful products than they do today...In the future it must be possible for companies to develop and market products which are demonstrably less harmful than the products of today. This is why regulation requires plenty of thought.’¹⁰²

The omission of harm reduction begs an interesting question in the ‘rights’ based context in which the FCTC evolved. Certainly there was no ambiguity as to the fact that everyone has a right to health, but it would seem that (on reading the FCTC text) such a right only exists for those who choose not to smoke. For those who continue to smoke, the issue of their right to health is ambiguous. This is because, correspondent with a reluctance to admit that some

¹⁰¹ WHO Tobacco Free Day ...

¹⁰² MandagMorgen, 16 October 2006 Interview with Derek Yach: The world’s true state of health is shocking

tobacco products are less risky than others, is a need to ring fence information that could allow genuine educated choices to be made. This essentially leaves consumers with compromised rights in that they may be essentially prevented from making a safer choice on the grounds of science. By neglecting to integrate harm reduction into the FCTC, officials are making an arbitrary decision that consumers don't indeed have a right to a safer option and again it comes back to the 'quit or die' choice that underpins the current regulatory approach. To paraphrase George Orwell in *Animal Farm* it's a bit like saying 'all rights are equal but some are more equal than others.'

Moving forward on tobacco product harm reduction

It has been established that the FCTC itself does not deal with the specifics or recognition that tobacco product regulation or harm reduction is a significant human right absent from the FCTC. There is one published article (that I have found) that recognises this view and it states that harm reduction and the international human right to health is the missing fourth pillar to the FCTC, along with prevention, protection and cessation: 'while successful in its execution fails to acknowledge the harm reduction strategies necessary to help those incapable of breaking their dependence on tobacco.'¹⁰³

The FCTC Preamble (the overriding principles of the treaty) states that the Parties to the Convention are 'Determined to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations,'¹⁰⁴ It then goes on, in Article 1, to define tobacco control as meaning '...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;'¹⁰⁵ Yet despite this the FCTC product guideline currently being developed in support of the FCTC does not specifically address the harm reduction issue.

The first meeting of the FCTC Conference of the Parties (COP) took place in February 2006 and at that meeting it was agreed that two protocols would be elaborated, one on measures to prevent illicit trade and one on preventing cross border advertising, promotion and

¹⁰³ Meier & Shelly

¹⁰⁴ FCTC Preamble

¹⁰⁵ FCTC Article 1

sponsorship; and two sets of guidelines would be developed, one for dealing with environmental tobacco smoke and one for guidelines on product regulation.

A working group on developing FCTC tobacco product regulation guidelines was established by the WHO under the auspices of the interim secretariat to the FCTC Conference of the Parties comprised of representatives of WHO member states. Throughout 2006 and 2007 the working group met and at the 2nd Conference of the Parties (COP2) meeting in July 2007, it will outline progress toward establishing a future regulatory framework for tobacco products. The legal framework for future international tobacco product regulation has been created and all that is required is for a significant number of COP members to indicate that harm reduction is a necessary element for inclusion in deliberations moving forward. However, given the prevailing political agenda it remains to be seen if any country does put ‘its head above the parapet’. The concept of harm reduction has recently been recognised as a pragmatic policy in two leading tobacco control countries (South Africa and Canada) and both are considering carefully public health impacts of tobacco use and have for example recently enabled the sale of snus in their markets - and this month we saw Marlboro snus launched in the USA. Will any of these countries go so far as to raise these issues at COP2 as a direction of importance for international public health policy or will they just continue to pursue it nationally?

Conclusion

The FCTC is undoubtedly a unique treaty and stands as a testament to what can be achieved through a combination of global activism, carefully managed political momentum, strong multilateral leadership and the existence of a genuine health problem: a legal product with potentially deadly side-effects. Despite the fact that the final draft is a mere shadow of its initial language, it has a practical reach and a rhetorical symbolism that will continue to inspire and drive tobacco control policy for many years. Also of significance is the fact that the FCTC has created precedents that have had a marked impact on factors as diverse as corporate conduct to NGO strategy in accessing negotiations. In some respects the FCTC was an articulation of a trend that had been percolating through the UN system for some time: a trend towards trying to marry international and domestic policy initiatives to bring about greater international coherency in rights/health policy across the board.

While the FCTC is more domestically penetrating than other international treaties, (and certainly framework conventions) setting international precedents in areas most usually and historically the domain of the sovereign right of states, and that it encourages governments not to follow the norms of regulatory creation such as consultation with the industry that it seeks to regulate, and even that the germ of its inception was based on vested interests and political motivations; it still is an effective treaty that has not only achieved a high level of legal compliance effectiveness, it has changed the behaviour of States and individuals in those States toward the objectives in the treaty and it has had a measure of problem-solving effectiveness by reducing the consumption of tobacco use – achieving a positive result in all three areas of treaty effectiveness measurement.

However, the political nature of its deliberations and the flawed processes that were followed in its coming together led to the failure of the world's first health treaty to include the crucial element of reducing the harm of the product in the protection of human health; and this had the effect of non recognition of the rights of those that choose to use tobacco and nicotine delivery products to the right to make informed choices based on sound science and a known risk continuum, but rather declaring in the treaty that the only way to reduce the risk is to abstain - and in so doing does not establish human health rights for all which was the treaty's stated objective. The effect has been not only the denial of the right to choice or the right to information on which to base choice, but the right for research to be done to advance scientific knowledge to develop the information on which to understand and base risk decisions. The effect has also been, rightly or wrongly, to position the tobacco industry and pharmaceutical industry unequally in law by endorsing one product category over another without a clear regulatory framework for products both delivering nicotine to consumers.

The legal framework for rectifying this situation is available. International law processes are currently unfolding as the FCTC Conference of the Parties comes together to determine the right course for tobacco product regulation - that will in due course impact globally in all State Parties. WHO member states can legitimately introduce harm reduction concepts and the pragmatic policy approach through these channels so as to ensure international standards on tobacco product regulation fully address public health concerns through in-depth research by leading scientists and medical institutions charged with robust consideration of the issues of tobacco and nicotine science - all that is required is political will.

But FCTC aside, decades of distrust between the public health community and the tobacco industry continue. Distrust has led to court decisions, regulatory actions at national and international levels and media responses that continue to isolate the tobacco industry from public policy debates. The major reason cited for this is that the tobacco industry has in the past done much to avoid, and thwart introduction of, effective public health action that would reduce the harm caused by consuming their products. A consequence of these actions and behaviours is that public sector tobacco scientists have taken active steps to avoid interaction with tobacco industry scientists. This, despite the contention that, as Meier & Shelly write, ‘the international right to health supports a harm reduction approach to tobacco control, and that working under the FCTC Framework countries should create international mechanisms to research and regulate harm reduction products and programs.’

The tobacco industry confronts an interesting conundrum in all this. Much of the activism and outrage that generated the FCTC was in response to allegations that tobacco companies misled consumers as to the dangers associated with tobacco and deliberately made products that were as addictive as possible. The spectrum of new regulation has tried to avoid any possible replication of this conduct by insisting on full information disclosure, prohibiting advertising and initiating a process for product regulation. On the one hand the restrictions may be justified, but on the other they will likely act to prevent tobacco companies from being able to educate consumers about relative risk and may even prevent the development and sale of safer products. The regulatory environment could freeze in place the current commercial model utilised by tobacco companies and leave consumers who don’t accept the ‘quit or die’ message rather worse off. It would be hard to know where to place the blame – on companies which are the natural and understandable target or on officials who refuse to let real world practicalities interfere with the uncompromising policy paradigm to which they are committed.

It would take extraordinary leadership on the part of a few WHO member states for harm reduction to become an integral part of the FCTC agenda going forward. The opportunity exists legally through the elaboration of protocols and guidelines to the FCTC currently underway but may diminish sooner rather than later given that the FCTC Conference of the Parties process is now well advanced in setting the future FCTC work programme. Perhaps it

will take a collective of global thought leaders to bring on the debate? This is a time and an opportunity for the international health community to take leadership for the future benefit of public health.

‘We can reduce tobacco related death and disease far more rapidly than we can reasonably expect to reduce nicotine use by focusing on the fact that people smoke for the nicotine but die from the smoke. Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.’¹⁰⁶

14,995 words (including footnotes)

¹⁰⁶ Tobacco Harm Reduction: how rational public policy could transform a pandemic *International Journal of Drug Policy* 2007 David Sweanor, Faculties of Law and Medicine, Unveristy of Ottawa, doi:10.1016?j.drugpo.2006.11.013

Bibliography

Articles/Papers/Journals

1. **Ballin S:** Making regulation of tobacco products work in a changing environment, comments of Scott D. Balling, the Alliance for Health Economic and Agricultural Development, New York, May 23, 2007
2. **Bettcher D and Lee K:** Globalisation and public health, *Journal of Epidemiology and Community Health*, January 2002, Vol 56, No 1
3. **Bodansky D:** Framework Convention on Tobacco Control, Technical Briefing Series, What makes international agreements effective? Some pointers for the WHO FCTC, School of Law, University of Washington, WHO, TFI, 1999
4. **Brownsword R:** What the world needs now: Techno-regulation, human rights and human dignity,
5. **Crow M:** Smokescreams and State Responsibility: Using human rights strategies to promote global tobacco control, *The Yale Journal of International Law*, Vol 29: 209, 2004
6. **Foulds J and Kozlowski L:** Snus – what should the public health response be? *The Lancet* Vol 369, June 16, 2007
7. **Frieden T and Bloomberg M:** How to prevent 100 million deaths from tobacco, *The Lancet*, Vol 369, May 19, 2007
8. **Gostin L:** The international health regulations – a new paradigm for global health governance? *First Do No Harm* - chapter 5
9. **Gray N and Kozlowski L:** More on the regulation of tobacco smoke: how we got here and where next, *Review, Annals of Oncology* 14: 353-357, 2003
10. **Hyde R:** European Parliament slammed over tobacco talks, *World Report, The Lancet* 2007: 367: 731-732
11. **Jacob G:** Without Reservation, *Chicago Journal of International Law*, Vol 5 No 1 Summer 2004
12. **Kozlowski L:** Smokeless tobacco stirs health debate, interview, *National Public Radio*, December 2006
13. **McGinnis J:** The political economy of global multilateralism, *Chicago Journal of International Law*, 1999
14. **McNeill A:** Harm Reduction, *British Medical Journal*, 2004, 328: 885-887
15. **Meier B:** Breathing new life in the Framework Convention on Tobacco Control: smoking cessation and the right to health. *Yale Journal Health Policy Law Ethics* 2005: 5:
16. **Meier B & Shelly D:** The Fourth Pillar of the FCTC: Harm Reduction and the International Right to Health, *Centre for Health Policy at Columbia University, Public Health Reports* September-October 2006, volume 121
17. **Myers M:** Could product regulation result in less hazardous tobacco products?, 3. *Yale Journal of Health Policy, Law and Ethics*, Winter 2002
18. **Oxman A:** Use of evidence in WHO recommendations, *The Lancet*, 9 May 2007
19. **Rodu B:** How Swede it is – making smoking history in Scandanavia, *Historical supplement to a presentation by Dr Brad Rodu, Professor, Department of Medicine, University of Louisville, USA* 2007

20. **Roemer R and Taylor A:** Origins of the WHO FCTC Global Tobacco Control Issues, *American Journals of Public Health*, June 2005, Vol. 95, No 6
21. **Shaffer E, Brenner J, Houston T:** International trade agreements: a threat to tobacco control policy, *Tobacco Control Journal*, 2005: 14
22. **Swanor D et al-** Tobacco Harm Reduction: how rational public policy could transform a pandemic *International Journal of Drug Policy* 2007
23. **Warner K:** Tobacco harm reduction: Promise and perils, *Commentary, Society for Nicotine and Tobacco Research*, 2002
24. **Williamson CH.** Clearing the smoke: addressing the tobacco issue as an international body. *Penn State International Law Review* 2002: 20: 587-615
25. **Yach D:** Injecting greater urgency into global tobacco control, *British Medical Journal, Tobacco Control* 2005: 14 – 145-148
26. **Yach D:** The world's true state of health is shocking, *Interview with MandagMorgen*, 16 October 2006

Books

1. **Aust A:** *Modern Treaty Law and Practice*, Cambridge University Press, 2004
2. **Schechter M:** *United Nations-sponsored World Conferences, focus on Impact and Follow-up*, United Nations University Press, 2001
3. **Scruton R:** *WHO, What and Why?*, Transnational Government, Legitimacy and the WHO, Institute of Economic Affairs, 2000

Legislation/Cases

1. Public Health (Tobacco) (Amendment) Act 2004 (UK)
2. Health Bill 69, 2007 (UK)
3. Senate Bill. 625: (USA)
4. Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004 Statutory Rules 2004 No. 264 (Australia)
5. Tobacco Control Act 6/2002 (Australia)
6. The Tobacco Advertising and Promotion Act 2002 (UK)
7. CLA 9615/05, *Irit Shemesh v. Fucachetta Ltd.* rendered July 5, 2006 (Israel)
8. Council Directive (EC) 2001/37 - Tobacco Product Directive
9. WHO Framework Convention on Tobacco Control (FCTC) (adopted 21 May 2003, entered into force 27 February 2005) World Health Assembly Resolution 56.1.
10. World Health Assembly Resolution 52.18
11. Charter of the United Nations
12. Universal Declaration of Human Rights (adopted December 1948, UNGA Res 217 A (III) (UDHR))

Websites

1. www.who.org
2. <http://web.israelinsider.com/Articles/Briefs/8837.htm>.
3. http://www.ias.org.uk/resources/publications/theglobe/globe0503_0601/g105030601_p14.html
4. <http://www.who.int/hhr/readings/treaties/en/index.html>
5. <http://www.who.int/hhr/readings/treaties/en/index.html>
6. <http://www.un.org/Depts/dda/WMD/treaty/>
7. http://www.unodc.org/unodc/en/drug_and_crime_conventions.html,
8. http://www.unodc.org/unodc/en/drug_and_crime_conventions.html
9. <http://www.basel.int/>
10. http://www.who.int/gb/fctc/E/E_inb2.htm)
11. <http://jech.bmj.com/cgi/content/full/60/9/751>
12. www.in.gov/attorneygeneral/legal/litigation/msa.pdf .
13. <http://www.ceche.org/mol/Winter-05/jump-1.html>)
14. <http://multinationalmonitor.org/mm2005/052005/interview-yach.html>)
15. http://womenshistory.about.com/od/brundtland/Gro_Harlem_Brundtland.htm)
16. www.paho.org/English/AD/SDE/RA/Guide2_MovementBuilding.pdf).
17. <http://ag.ca.gov/tobacco/resources/msasumm.php>
18. <http://academic.udayton.edu/health/syllabi/tobacco/summary.htm>)
19. <http://www.stopcorporateabuse.org/cms/page1144.cfm>)
20. <http://www.nature.com/embor/journal/v5/n1s/full/7400226.html>
21. www.who.int/gb/fctc/PDF/inb1/e1inbcp13.pdf).
22. www.who.int/entity/tobacco/media/en/unreportII.pdf “
23. <http://www1.worldbank.org/tobacco/presentation.asp>:
24. <http://www.who.int/mediacentre/factsheets/fs172/en/index.html>
25. www.bat.com
26. www.theeconomist.com
27. www.acsh.org/healthissues/newsID.1531/healthissue_detail.asp
28. http://www.who.int/tobacco/fctc/conferences/oslo_final/en/print.html.
29. http://www.who.int/tobacco/communications/events/tob_harm_reduction/en/index.html