RESEARCH PAPER

Ethical and legal aspects of global tobacco control

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On 28 February 2005, the Framework Convention on Tobacco Control came into force as a result of at least 40 countries becoming State Parties through ratification of this first ever health treaty sponsored by the World Health Organization. This article discusses the bioethical, trade, and legal aspects of global tobacco control. Special emphasis is given to globalisation of tobacco use and the challenges it poses to sovereign nations. It also advocates a bioethical basis in the pursuit of global solutions to expanding tobacco use.

In 2003, the world responded to a new epidemic of what came to be known as severe acute respiratory disease syndrome (SARS), which caused thousands of deaths over several months. The World Health Organization, under Article 2d of its constitution,[1] led a global emergency effort to rapidly identify the causative viral agent, epidemiological characteristics of transmission, and control measures necessary to contain successfully the epidemic.[2] Imagine, though, that the nation in which the epidemic originated refused to cooperate in an international effort to control the spread of SARS. Imagine that despite the overwhelming scientific evidence for effective control measures, global support for these was hesitant or absent. Finally, imagine that the vectors for the disease were profitably traded internationally, and that to preserve this trade or to open new markets these vectors were smuggled into new markets; once successfully marketed across borders, international agreements or treaties protected legal trade in them despite the advice of public health experts to restrict their trade. Clearly, these circumstances would create public revulsion and outcry, as well as diplomatic strife among affected nations. Such events would also suggest that bioethical principles of international health cooperation were violated, that business ethics on the part of involved companies were appalling, and that international cooperative governance had failed.

Granted, SARS was an infectious disease emergency requiring international cooperation and control measures. But one may argue that tobacco use is also an emergency worthy of immediate global responses, even though the epidemic is now 500 years old and only slowly progressive in nature. Nevertheless, the need for an ethical perspective and legal approaches to preventing the rapid globalisation in tobacco use call for an emergency response. This response must be based on ethical principles, international collaboration, and shared governance. The Framework Convention on Tobacco Control (FCTC), a health treaty negotiated over five years, represents the global emergency response to the global epidemic of tobacco use.

Globalisation of tobacco use and the ensuing disease burden impugns national governments' sovereignty to protect the health of their populations.[3] Globalisation and its public health implications now are prolifically analysed, especially with regard to emerging and re-emerging infectious diseases, environmental degradation, and bioterrorism. It is thus timely to consider tobacco caused illnesses within this same global health perspective. Under Article 2k of it constitution, WHO led the development of the FCTC as the first ever global public health treaty.[4] The treaty was approved by consensus for submission to member states for signature and ratification at the May 2003 World Health Assembly, and in less than a year and a half, 40 countries from all regions of the world have taken the necessary steps to become contracting parties to the treaty (see http://www.who.int/tobacco/fctc/signing_ceremony/countrylist/en/ for an updated list of signatories and ratifications).

The FCTC emphasises that contracting states have the right to protect their populations' health, that individual rights should be respected, and that the ''widest possible international cooperation is necessary to control tobacco-caused illnesses''.[5] However, there is no specific mention of the bioethical basis for this global approach to tobacco control. This paper discusses the bioethical basis for cooperative approaches to the global tobacco epidemic. In addition, it discusses the use of international legal instruments to address global public health threats, and the ethical basis for implementation of the FCTC.

BIOETHICAL BASIS FOR GLOBAL TOBACCO CONTROL

There are four main principles of bioethics that apply to tobacco control: autonomy, beneficence, non-maleficence, and justice.[6] Persons are deemed to have autonomy on the basis of their nature as rational and moral beings. Preservation of individual autonomy requires both information about a health risk behaviour, and voluntary choice (that is, without nicotine addiction). Beneficence is the obligation for national governments to promote public well being, and non-maleficence refers to the obligation of

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Abbreviations: FTCT, Framework Convention on Tobacco Control; GATT, General Agreement on Tariffs and Trade; SARS, severe acute respiratory syndrome; TTCs, transnational tobacco corporations; WHO, World Health Organization; WTO, World Trade Organization

governments to avoid harm (embodied, for example, in the ''Precautionary principle'', by which a government may preclude population exposure to a likely hazard even without absolute proof of the hazard).[7] The principle of justice requires the fair and equitable distribution of social goods and, accordingly, the fair and equitable distribution of social and biological burdens.[8 9]

Death from tobacco use represents the single most preventable cause of death in the world. Half a billion of the world's current population will die from tobacco related deaths, with 250 million of these people dying in middle age. By 2030, 16% of all adult deaths (10 million a year) will be directly caused by tobacco use, with 70% of these deaths occurring in low income countries. By 2100, one billion deaths will have occurred globally directly because of tobacco use.[10] Given this disease burden, there is a clear ethical mandate for global cooperation in tobacco control.

GLOBALISATION OF TOBACCO USE

Globalisation of tobacco use and the ensuing disease burden impugns national governments' sovereignty to protect the health of their populations.[3] Globalisation can be defined in a general sense by how populations behave across three major dimensions: spatial, temporal, and cognitive.[11] Spatially, globalisation refers to the reduced influence of national borders, with the free movement of goods and people across them. International trade in legal products freely crosses borders, as do advertising, information on the internet, and environmental pollutants. These can all impact economic, political, cultural, technological, and health sectors, and they erode the national sovereignty that depends on borders. This effect on sovereignty suggests that nations need to address cross border health threats through some form of international governance.[12] Temporal dimensions of globalisation involve the shortened time for communications and travel, which may be beneficial in terms of the rapid transmission of information, and also a threat in terms of the rapid spread of infectious disease or marketing of hazardous products such as tobacco. Cognitively, globalisation may redefine culture, self image, and market demand through product imagery and social learning.

In the case of tobacco, cognitive globalisation shapes mental frameworks on tobacco use around modernity, prosperity, and ''western'' values. These create an image of a ''global smoker'' who smokes internationally marketed brands. Four companies' global brands now occupy 75% of the world's tobacco market, and Marlboro alone accounts for 8.4% of all cigarettes sold in the world. Marlboro's success is due to Philip Morris' (now Altria) extensive marketing, advertising, and brand stretching worldwide.[13] Indeed, the Marlboro Man image has been considered by *Advertising Age* to be the number one advertising icon of the last century.[14] Cognitive globalisation is also supported by illegal smuggling of global brands and by systematic policy interventions, including concentrated efforts to forestall any international agreements, international governance efforts, and regulation at national or international levels. Ethically, cognitive globalisation of tobacco products threatens the autonomy of nations and their ability to protect the health of their citizens. It also violates the principle of non-maleficence insofar as there is no safe level of tobacco use and thus any promotion of trade in tobacco is in effect malevolent.

The efforts by the transnational tobacco corporations (TTCs) at the global level divert attention away from the health and economic impact of tobacco use and effectiveness of policy interventions to control tobacco. Instead, the TTCs consistently emphasise that national governments should address tobacco control policies for only adults (because it is a legal product) and focus any public health efforts only on children. Globalisation of tobacco use depends largely on advertising, image development, and liberalisation of trade. Without global regulatory approaches, this cross border spread of misinformation will continue to support demand for tobacco use unless counterbalancing information can be disseminated. Those with the least access to information, with the least ability to seek treatment or counselling, and the most vulnerability to nicotine addiction need the counterbalancing effects of multinational tobacco control efforts. This is clearly a social justice ethical perspective, requiring governments to assert the principle of beneficence in developing policies to control trade, marketing, and globalisation of tobacco use.

FREE TRADE AND GLOBAL TOBACCO USE

Trade liberalisation has significantly increased tobacco use, particularly in low and middle income countries.[15] Under the aegis of free trade, increased competition leads to reduced prices and increased marketing efforts for all traded goods. However, nations may apply a variety of trade protections, including tariffs, quotas, and price supports for locally grown agricultural products. In addition, marketing restrictions, licensing, restricted product lists, foreign exchange controls, content requirements, and production subsidies are also used to protect national agricultural products and markets. However, these national trade policies do not pretend to focus on health as the basis for intervention; they are primarily intended to protect state monopolies in certain products and to support national agricultural product markets. Thus, there is also a need to consider how trade and health might interact to support the national self interest of poor countries that suffer most from the globalisation of tobacco marketing. One might even consider that the World Trade Organization (WTO) would be a multinational venue in which health and trade concerns could be reconciled.

However, the WTO rules were established to support non-discriminatory treatment of domestic and foreign products and not to support any agendas in human rights or public health protections.[16] Public health authorities do not participate in these negotiations. The goals for these rules are to eliminate trade barriers and to settle disputes through WTO tribunals. Increased trade through liberalisation of international markets is supposed to improve global welfare. However, free trade may primarily benefit the industrialised nations, and thus a more equitable distribution of these gains throughout poor nations is justified. An even more important consideration for social justice is that the costs of those gains should be more evenly distributed. The responsibility for alleviating the costs of tobacco related disease and disabilities among populations of low income countries should perhaps be shouldered by those countries that might benefit the most from free trade in tobacco products. This is an ethical consideration rarely raised in free trade negotiations.

In the 1994 Uruguay round of General Agreement on Tariffs and Trade (GATT) negotiations, tobacco product tariff rates among developed nations were reduced by more than half, from an average of 22.1% to 10.2%.[17] Since then, there has been a clear increase (42% between 1993 and 1996) in global exports of tobacco products; globally, tobacco consumption was found to be on average 10% higher than it would have been in the absence of these actions.[18] GATT has then violated the principle of non-maleficence by supporting the increase in consumption of a known, but legal, health hazard.

Public health concerns should be grounds for restrictions on free trade, even if raising these concerns may impede market liberalisation for some imported goods (that is, those that are clearly harmful to health).[19] Article XX(b) of the GATT states that countries may take exceptions to treaties if

Table 1 International agreements relating to health and harmful substances

Issues addressed	International instruments	Public health implications
Weapons	Ottawa Convention on the Prohibition of the Use, Stockpiling, Production, and Transfer of Anti Personnel Mines and on Their Destruction	Reductions in injuries, death, and disabilities due to land mines, especially in post-conflict situations
Drugs and medical devices	US Food, Drug, and Cosmetic Act	Restricts export of drugs and devices not approved for use in the USA
Narcotic and psychotropic drugs	Single Convention on Narcotic Drugs (1961) UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)	Limits trade in psychotropic drugs to prevent illegal sales and use
Persistent organic pollutants	Stockholm Convention on Persistent Organic Pollutants (2001)	Governs production, use, and trade in substances that accumulate in the environment and pose a substantial threat to human, animal, and plant life
Hazardous waste	Basel Convention on Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1989)	Governs production, transportation, storage, management, and disposal of hazardous waste. Prohibits import or export of hazardous wastes to non-parties
Endangered species	Convention in International Trade in Endangered Species of Wild Fauna and Flora (1972)	Strict controls on trade in covered species, completely banned in threatened species

Adapted from *Public health and international trade, volume II: tariffs and privatization*. Washington DC: Campaign for Tobacco-Free Kids, 2002.

adherence to them may result in human, animal, or plant loss of either life or health. Under this provision, France successfully defended its refusal to import asbestos. This has been the single case of a positive finding by WTO tribunals citing health over trade liberalisation. While there may be at least a theoretical concession for human health, provisions favouring trade over health seem to be more numerous, or at least more frequently upheld by the WTO. Since its inception, Article XX(b) has not been supported in at least 10 other instances. In addition, there exist many provisions that seem to err on the side of trade.[20] The article actually calls for a high degree of scrutiny to be applied to measures that could restrict trade in tobacco products. These must be shown as essential to protect public health without supporting asymmetric discrimination against imported products. In order to support trade restrictive policies, public health advocates must be able to show evidence that other efforts to reduce tobacco could be used instead of trade restrictive policies. However, there is growing consensus among health groups that tobacco is not like any other freely traded product in that when used as designed, it is uniquely addictive and lethal. These groups advocate that restrictions in tobacco trade should be added to product specific trade rules that address other public health, environmental, and security threats.[21] Principles of beneficence and non-maleficence apply to these considerations.

EXISTING LEGAL AGREEMENTS TO CONTROL TRADE IN HARMFUL GOODS

International agreements are used to address public health threats and may be considered a form of ''global public goods''. These agreements are used to control the spread of infectious diseases such as cholera, yellow fever, and plague (addressed by the current version of the International Health Regulations),[22] or they may be used to restrict trade in weapons, drugs and medical devices, persistent organic pollutants, hazardous wastes, or endangered species (table 1). They also address food safety and under WTO structures, permit measures to protect public health (Committee on Sanitary and Phytosanitary Measures). In addition, there are more than 20 multilateral treaties relating to environmental issues that include trade restrictions. With respect to the International Health Regulations these mainly exist to preserve, and not inhibit, international trade.[23]

Implementation of these international agreements depends on harmonisation of national legislation to support the covenants of the treaties. In other words, when the treaties are signed and ratified by national legislative bodies, national legislation must be developed that will accommodate the elements of these treaties. Such has been the case for some nations who signed the FCTC; ratification may depend on implementation of national legislation to harmonise with the provisions of the FCTC. This is where the issue of national sovereignty arises and why so many nations hesitate to sign treaties that either do not permit reservations according to national policy or are not likely to achieve the political support necessary at the domestic level. Health systems and tobacco use are legislated according to national boundaries, but the globalisation of tobacco is a trans-border phenomenon akin to the trans-border spread of infectious diseases. Indeed, one may think in terms of the classic host–vector–environment relationship for infectious diseases, where tobacco use is taken up by a susceptible host (usually a child) through the influence of a globally active vector (TTCs and their trans-border advertising and marketing influences) in an environment that may have little in the way of equitable information (lack of product warnings) or restrictions on dissemination (lack of advertising and promotion bans and lack of restrictions on passive smoke exposure). Clearly, these are reasons to consider a bioethical approach to global tobacco control, supported by legal measures such treaties and trade agreements.

Globalisation is transforming sovereignty. As Kickbush and Buse have argued,[3] the public interest must be protected through a new form of international governance based global market frameworks that address human rights, labour standards, and environmental respect. In addition, such frameworks must also recognise the bioethical basis for global approaches to global health problems.

BIOETHICAL BASIS FOR THE FCTC

The limitations of global governance through trade agreements and through international health cooperation to address the tobacco epidemic are the main reasons to consider the multinational treaty approach of the WHO's FCTC. The debates surrounding this first ever international health treaty recognised the need to extend health actions beyond traditional public health education, health promotion, and epidemiology. A multinational approach is needed to address trade, information, and environmental policy through economics, legal, and environmental sectors for the WHO member states.[24] At the national level, the TTCs consistently undermine effective tobacco control measures, especially those that may be established through legislation. Just as globally active infectious diseases strain the ability of nations and international organisations to control them, the TTCs inhibit national and international processes to control a truly global threat. Even within the WHO, there has been

evidence of a broad range of TTC interference with efforts to address global tobacco control.[24]

As stated above, no mention is made of the bioethical basis for the FCTC. However, in an analysis of the FCTC and its enforcement through existing human rights treaty bodies,[25] Crow contends that the FCTC recognises the importance of the human rights regimens embodied in the International Covenant on Economic, Social, and Cultural Rights; the Convention on the Elimination of All Forms of Discrimination Against Women; and the Convention on the Rights of the Child. These conventions all link to individual rights to health, life, and freedom of information inherent in the principle of autonomy. In addition, she goes on to describe how the Inter-American Court of Human Rights addressed due diligence standards to assure state responsibility at an international level to preserve human rights abuses by private entities. Governments must, in the pursuit of non-maleficence, exercise some degree of control over the activities of private companies and especially over those with state ownership. Smokers and potential smokers must be fully informed of all the risks of the hazards of smoking, the addictive nature of nicotine in tobacco, and the dangers of exposure to passive smoking in order to level the playing field for all populations.

These dangers are not fully realised, especially by the poor and the young, thus leading to asymmetry of information that precludes informed choices.[26] Information asymmetry causes markets to become inefficient, since all the market participants do not have access to the information they need for their decision making processes. This asymmetry is a violation of the principle of justice, which can subsequently lead to the asymmetrical consequences of tobacco use for low income countries as cited above. Social inequities in tobacco use and tobacco attributable health consequences have been well established.[27 28] These consequences require states to take global action to address the needs of the poor, whose welfare will be neglected without directed state actions to preserve human rights, thereby addressing equity and health related to tobacco use. Finally, the principle of beneficence requires that states who either support or benefit from the presence of TTCs take affirmative measures to ensure that public health overrules trade in potential disputes on tobacco tariffs and marketing. In addition, technical assistance and information for tobacco control should be transferred to help alleviate the effects of TTC policy and misinformation efforts in low income countries. Although this provision was not included in the final draft of the FCTC, it seems relevant to the ethical arguments referenced here.

The FCTC as currently drafted is more a guideline for international cooperation and national policy development rather than a rigidly detailed international treaty. As such, protocols will be drafted that will have more detailed binding obligations, perhaps focusing initially on smuggling, labelling, and advertising restrictions. This is to be expected, and it is within these subsequent negotiations that states can craft effective international governance on tobacco as a global health threat. The question is, given the limited specific obligations and strong consensus on the overall objectives of the FCTC, why would any country not participate in global tobacco control efforts embodied by the FCTC?

The Secretary of the US Department of Health and Human Services signed the FCTC, but it is unclear whether there is any intention on the part of the US Congress (or the current Bush Administration) to ratify this critical health treaty. Traditionally, many US foreign policies have been based on moral arguments,[29] emphasising values inherent in the American ethic and encouraging other nations to support these. The USA has also emphasised human rights for all its citizens. Finally, the USA has had some of the greatest successes at implementing tobacco control policy of any nation. Thus it is ethically inappropriate for the USA not to take a principled, visible, financially committed, and vocal role in international tobacco control. However, in our judgment, unless its legislators hear from the electorate that this is a high priority, US policy is not likely to change; there are simply too many other pressing global problems, including fighting terrorism, stopping bioweapon construction, and underwriting nation building. Nevertheless, tobacco also poses a major threat, and will probably kill more people globally than any of these threats combined. Hence, to ignore the burden of tobacco control is to permit an unconscionable global health emergency.

What this paper adds

This paper brings together concepts of globalisation, bioethics, and international governance with respect to the Framework Convention on Tobacco Control (FCTC) deliberations. It asserts that there is a moral imperative to encourage the member states of the World Health Organization to sign and ratify the FCTC.

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