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A Report of the CSIS Global Health Policy Center

AUTHOR
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Center for Strategic and International Studies
1800 K Street, NW, Washington, DC 20006
Tel: (202) 775-3119
Fax: (202) 775-3199
Web: www.csis.org

U.S. ENGAGEMENT IN INTERNATIONAL TOBACCO CONTROL

Benn McGrady[1]

Summary

Greater U.S. engagement in international tobacco control efforts could bring benefits for global health on issues relating to surveillance and monitoring, illicit trade, and product regulation. Engagement could also benefit the United States in at least three ways. First, U.S. engagement with new international negotiations concerning illicit trade in tobacco products could ultimately help reduce domestic tax evasion and improve national security by addressing this trade as a potential source of funding for terrorist organizations and organized crime. Second, international efforts relating to product regulation could feed into proposed U.S. regulatory processes and increase the chance of international standardization. Third, long-term and serious engagement with tobacco control could provide a significant payoff in restoring the U.S. reputation on tobacco issues, a reputation badly tarnished by past U.S. support for the expansion of tobacco markets in developing countries. To be taken seriously, however, the United States would have to begin with Senate ratification of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC)[2] and by being sensitive to foreign health authorities' use of the convention as an advocacy tool in their own domestic debates on tobacco control.

U.S. ratification of the FCTC is not likely unless domestic legislation is passed requiring the use of stronger health warnings on packaging and more comprehensive bans on tobacco advertising. The House of Representatives recently passed a bill that would have this effect. That bill remains to be passed by the Senate, after which ratification of the FCTC may become an objective of the Obama administration.

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[1] Benn McGrady is an Australian attorney and policy consultant who advises civil society groups on issues of global health and international trade.

[2] World Health Organization (WHO), *WHO Framework Convention on Tobacco Control* (Geneva: WHO, May 21, 2003), http://www.who.int/fctc/text_download/en/index.html.

Background

In 2008, Senator Barack Obama signed a letter to President George W. Bush calling for the president to present the FCTC to the Senate, requesting ratification. Now that President Obama is in office, there is a growing expectation that the United States will become a party to the convention. While this is likely to be a positive development, formal ratification of the FCTC is merely the beginning of U.S. engagement on international tobacco control issues. Policymakers and others who wish to see greater U.S. engagement should begin considering how the United States can best contribute to tobacco control efforts, the potential payoffs associated with that contribution, and the potential risks that U.S. engagement might pose to international tobacco control efforts. This paper sets out the key issues in these debates and provides a brief analysis of the potential contributions, payoffs, and risks.

Before considering these issues in further detail, it is worthwhile to examine the historical context in which the FCTC was developed and the role that the United States played in that process.

The United States was an undoubted leader in the initial stages of tobacco control. The 1964 report, Smoking and Health: Report of the Advisory Committee to the Surgeon General,[3] triggered a major shift in awareness about the harmful impact of tobacco consumption on health. This report, which achieved international renown, set out the evidence base supporting regulatory interventions such as the introduction of health warnings on packaging in 1965 and bans on tobacco advertising on television and radio in 1969.

However, since these initial measures, domestic debates have persisted about the extent to which stronger measures are appropriate. While other countries have implemented measures such as large pictorial health warnings and bans on tobacco advertising in various forms, the U.S. approach to tobacco control has not been as comprehensive. Concerns about paternalism and the influence of industry have meant that much progress at the domestic level has been made through alternatives to regulation, such as litigation.

The interests of the tobacco industry were also evident in U.S. foreign policy. The foreword to the FCTC states that it was "developed in response to the globalization of the tobacco epidemic" and that:

> [t]he spread of the tobacco epidemic is facilitated through a variety of complex factors with cross-border effects, including trade liberalization and direct foreign investment. Other factors such as global marketing, transnational tobacco advertising, promotion and sponsorship, and the international movement of contraband and counterfeit cigarettes have also contributed to the explosive increase in tobacco use.

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[3] Advisory Committee to the Surgeon General, *Smoking and Health: Report of the Advisory Committee to the Surgeon General* (Washington, D.C.: GPO, 1964), http://profiles.nlm.nih.gov/NN/B/B/M/Q/_/nnbbmq.pdf.

In essence, this message reflects the demographic shift of tobacco consumption from industrialized countries to developing countries. Although U.S. manufacturers and government authorities were not entirely responsible for this shift, the U.S. trade representative (USTR) was a visible symbol of the process. In the 1980s, the USTR was successful in active attempts to open Asian markets to U.S. tobacco products.[4] These attempts came into sharp focus in 1991 during a General Agreement on Tariffs and Trade (GATT) dispute between the United States and Thailand.[5] Subsequently, an influential publication commissioned by the World Bank concluded that trade liberalization had led to increased tobacco consumption in some low- and middle-income countries.[6] This context formed a backdrop to FCTC negotiations, where U.S. negotiators worked to water down the content of the convention.

Ultimately, the World Health Assembly adopted a framework convention that requires parties to implement a range of basic tobacco control measures including tax measures, labelling measures, and restrictions on advertising, promotion, and sponsorship. These and other basic obligations are to be supplemented over time through the development of more detailed provisions in guidelines and protocols.

U.S. Compliance with the FCTC: A Precursor to Ratification

Article 30 of the FCTC provides that no reservations may be made to the convention. As a consequence, even after Senate ratification, individual U.S. laws would still need to be brought into compliance with all FCTC provisions if the United States is to be in compliance with the overall convention. The requirements of greatest interest concern packaging and labelling and bans on tobacco advertising, promotion, and sponsorship.

Article 11 of the FCTC governs the packaging and labelling of tobacco products. Article 11.1(a) would require the United States to ensure that "tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions." The provision goes on to refer to descriptors such as "light" and "mild" as examples of tobacco labelling that may have this effect.

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[4] Frank Chaloupka and Adit Laixuthai, "U.S. Trade Policy and Cigarette Smoking in Asia," Working Paper 5543, National Bureau of Economic Research, Cambridge, Mass., April 1996.

[5] General Agreement on Tariffs and Trade (GATT), *Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes*, BISD 37S/200, Panel Report DS10/R, adopted November 7, 1990.

[6] Allyn Taylor, et al., "The Impact of Trade Liberalization on Tobacco Consumption," in *Tobacco Control in Developing Countries*, ed. Prabhat Jha and Frank Chaloupka (New York: Oxford University Press, 2000), pp. 343–364.

Article 11.1(b) of the FCTC would obligate the United States to require that product packaging carry health warnings describing the harmful effects of tobacco use. Among other requirements, these warnings must occupy at least 30 percent of the principal display areas of a package. At present, U.S. laws require the use of smaller textual warnings on the sides of tobacco products that do not meet this requirement. If the United States were to ratify the FCTC, it would have three years within which to implement the measures.

In the case of tobacco advertising, Article 13 of the FCTC would require the United States to undertake a comprehensive ban on all tobacco advertising, promotion, and sponsorship, including cross-border advertising, promotion, and sponsorship originating in its territory. This obligation is subject to the constitution or constitutional principles of a party, meaning that the United States would not be compelled to prohibit advertising, promotion, and sponsorship where to do so would violate constitutional rights. Article 13 is also supplemented by guidelines intended to assist parties in meeting their obligations under the provision.[7] While the status of current U.S. laws under Article 13 is obscured by constitutional considerations, a strong argument could be made to the effect that existing U.S. restrictions, which prohibit advertising on radio and television, are not "comprehensive" for purposes of Article 13.

Potential noncompliance with Articles 11 and 13 of the FCTC could, however, be remedied if the proposed Family Smoking Prevention and Tobacco Control Act is passed into law.[8] If passed, this law will have wide-ranging implications for U.S. tobacco control laws. In addition to addressing packaging, labelling, and advertising, the law would extend the powers of the U.S. Food and Drug Administration (FDA) to encompass regulation of tobacco products.

With respect to packaging and labelling, any new laws would come into effect 12 months after enactment. The act would, therefore, bring U.S. laws into compliance with Article 11.1 of the FCTC. Similarly, the act would authorize the secretary of health and human services to restrict advertising and promotion of tobacco products by regulation where appropriate to protect public health. This power would permit the secretary to implement measures that ensure compliance with Article 13.

Accordingly, if passed, the Family Smoking Prevention and Tobacco Control Act would alleviate concerns about whether U.S. laws are in compliance with the FCTC.

Failure to pass the act would bring U.S. ratification of the FCTC into question because another bill would be required in order to amend U.S. laws governing packaging, labelling, and advertising bans. Ratification is unlikely to proceed without prior amendment to domestics laws governing these issues because the implementation of such laws after ratification would not be guaranteed,

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[7] WHO, "Guidelines for implementation of Article 13 of the WHO Framework Convention on Tobacco Control (Tobacco advertising, promotion and sponsorship)," decision FCTC/COP3(12), http://www.who.int/fctc/guidelines/article_13.pdf.

[8] See H.R.1256; S.R. 982.

thereby exposing the United States to the possibility of violating a new treaty obligation. Progress of the bill is likely to be seen as a test of the support that could be expected in the event that the FCTC is sent to the Senate for ratification. As a consequence, the following analysis is based on the assumption that the proposed bill will be passed.

Contributing to International Tobacco Control

At present, there are three issues on which the United States is most capable of making a large contribution to international tobacco control. These concern illicit trade in tobacco products, product regulation, and surveillance and monitoring.

Illicit Trade in Tobacco Products

In July 2007, the Conference of the Parties (COP) to the FCTC established an intergovernmental negotiating body (INB) to negotiate a protocol to the FCTC addressing illicit trade in tobacco products. The first meeting of the body (INB1) was held in February 2008 and the second meeting (INB2) in October 2008. INB3 will be held in Geneva from June 28 to July 5, 2009. This meeting will be conducted over an eight-day period in an attempt to conclude negotiations. If, as expected, negotiations are not concluded at INB3, the parties will hold INB4 in early 2010. Irrespective of whether negotiations are concluded at INB3 or INB4, the parties have expressed an intention to present the text to the fourth session of the COP (COP4) for adoption in late 2010.

The United States has traditionally taken a leadership role in efforts to address transnational organized crime, including with respect to tobacco products. The United States was a leading proponent of the UN Convention on Transnational Organized Crime (UNTOC) and, in 2002, hosted WHO member states at the International Conference on Illicit Tobacco Trade.

U.S. reengagement with these issues in the context of protocol negotiations is important for a number of reasons. Illicit trade in tobacco products leads to large-scale losses of government revenues around the world and undermines the use of tax measures as a means of protecting population health. Illicit trade in tobacco products also poses an indirect threat to U.S. national security interests. A 2003 report by the U.S. General Accounting Office concerning sources of terrorist financing concluded that terrorist organizations such as al Qaeda, Hezbollah, and Hamas use trade in contraband cigarettes as a means of financing their activities.[9]

It is also worth noting that the timing of any U.S. ratification of the FCTC will affect the ability of the United States to participate in these negotiations. Article 36 of the FCTC provides that the convention shall enter into force for any party 90 days after the date of deposit of its instrument of ratification, acceptance, approval, or accession with the depository. Accordingly, if a final session of negotiations is to be held in early 2010, the United States must ratify the convention at least 90

[9] U.S. General Accounting Office (GAO), "Terrorist Financing: US Agencies Should Systematically Assess Terrorists Use of Alternative Financing Mechanisms," GAO-04-163, Washington, D.C., November 2003.

days prior to that session in order to participate as a party. Failure to become a party prior to that session means that the United States would be restricted to participating as an observer, would not possess a right to vote, and would be permitted to speak only after the parties.[10] As a matter of practice, this right to speak only after the parties could limit the ability of the United States to express its views prior to consensus being reached.

Product Regulation

Articles 9 and 10 of the FCTC govern regulation of the contents of tobacco products and tobacco product disclosures respectively. A working group of states that are parties to the FCTC will submit nonbinding draft guidelines on these issues to COP4. These draft guidelines have been a source of ongoing work since COP1 in February 2006 and might be adopted at COP4.

In the event that FDA powers are extended to encompass regulation of tobacco products, the United States will be well positioned to contribute to international efforts concerning product regulation and disclosures. A handful of developed countries with relatively sophisticated regulatory agencies are leading efforts in this area. Canada, the European Community, and Norway are the key facilitators of a working group preparing the draft guidelines, and 20 other states are acting as partners in this process.

Given that the United States was not a party when this working group was formed or when it was mandated to prepare draft guidelines, it is unclear whether it would be permitted to act as a working group partner once it becomes a party to the FCTC. A decision on any request to participate would probably be made either by the bureau of the COP or by the working group itself. Leaving the question of inter-sessional participation aside, the United States would be permitted to participate in discussion of the draft guidelines at COP4, and to vote on them, so long as it ratifies the convention at least 90 days prior to the meeting. In the longer term, as the regulation of tobacco products gathers speed, the United States, through the FDA, might play a leading role in international efforts relating to product regulation.

Surveillance and Monitoring

Since the FCTC came into force, the normative agenda of the COP has been fast paced. In its three sessions, the COP has initiated negotiation of a protocol on illicit trade in tobacco products and adopted guidelines on Article 5.3 (protection of public health policies with respect to tobacco control from commercial and other vested interests), Article 8 (protection from exposure to tobacco smoke), Article 11 (packaging and labelling of tobacco products), and Article 13 (tobacco advertising, promotion, and sponsorship).

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[10] Article 29.2, Rules of Procedure of the Conference of the Parties to the WHO Framework Convention on Tobacco Control.

As mentioned above, the parties will consider the adoption of an optional protocol at COP4, in late 2010, as well as the adoption of guidelines concerning product regulation and disclosures. In addition, at COP4 the parties will consider:

- draft guidelines addressing education, communication, training, and public awareness (Article 12);
- either a progress report or draft guidelines from a working group with respect to demand reduction measures concerning tobacco dependence and cessation (Article 14);
- a progress report from a working group or policy options and recommendations concerning economically sustainable alternatives to tobacco growing (Articles 17 and 18); and
- a technical report addressing price and tax policies (Article 6).

COP4 is likely to mark a turning point for the FCTC. Focus will shift to some degree from development to implementation of the substantive aspects of the convention. In this respect, there is little doubt that the FCTC has generated a significant amount of activity in the field of tobacco control at the domestic and international levels. However, the relatively weak reporting mechanism built into the convention and the absence of any monitoring body means that in many instances, the impacts of this activity have not been well identified.

The United States is a clear leader in the field of evidence-based policymaking and could, therefore, make a large contribution on these issues. Improved reporting and monitoring at the international level would go some way to ensuring that the policy choices made within that forum and at the domestic level are evidence based. In this respect, the formation of a body for the purposes of monitoring the progress of state parties and assisting parties in information gathering and reporting is particularly important.

At COP3, India proposed the establishment of such a body but received relatively little support from the parties for two primary reasons. First, the proposal was made from the floor of the meeting in an ad hoc fashion and without sufficient consultation of other parties. Second, the proposal failed to recognize the special difficulties faced by some developing countries in compiling information and mustering the resources required for reporting. While this issue is addressed in further detail below, it is worth noting here that the United States could make a significant contribution to the FCTC through leadership on the development of effective reporting and monitoring systems at the international level.

The Needs of Developing Countries

Developing countries have expressed disappointment at the failure of the FCTC to facilitate the provision of technical and financial assistance for tobacco control. Industrialized countries have responded by saying that developing countries must first identify their needs. The convention secretariat and WHO Tobacco Free Initiative are currently working with developing countries to assist them in this process.

In the future, technical and financial assistance is an area in which the United States could potentially make an important contribution.

Potential Domestic Benefits of U.S. Engagement

The need to address noncommunicable diseases is an important part of any global health strategy intended to enhance security. Although noncommunicable diseases do not pose as direct a threat to U.S. interests as communicable diseases, treatment of noncommunicable disease consumes scarce health care resources and undermines the capacity of health systems to respond to communicable diseases. This concern is particularly problematic in developing countries that have relatively weak health systems. Thus, U.S. efforts to minimize tobacco-related disease abroad support more targeted interventions such as those relating to the transmission of communicable disease.

There are also a number of more specific gains that the United States might make from positive engagement with the FCTC.

Illicit Trade in Tobacco Products

As described briefly above, efforts to address illicit trade in tobacco products can increase taxation revenues, enhance the effectiveness of tax-based health measures, and minimize access to finance for terrorist organizations and organized criminal groups. For these and other reasons, the proposed Family Smoking Prevention and Tobacco Control Act, discussed above, would amend the Federal Food, Drug and Cosmetic Act by empowering the secretary of health and human services to make regulations concerning prevention of illicit trade in tobacco products, including on issues such as record keeping and product markings. Since these issues are under negotiation in the FCTC context, the United States has an incentive to participate in order to foster standardization and minimize inefficiency that can be created by diverse national systems governing issues such as labelling.

The United States also has an interest in ensuring that a future illicit tobacco trade protocol complements existing international approaches that address organized crime without duplicating work carried out by other international organizations. The institutional expertise to support an instrument of this type lies in the UN Office on Drugs and Crime (UNODC) and not within the WHO. Accordingly, the question of how the illicit trade protocol will relate to UNTOC is important to ensuring the effectiveness of both the UNODC and the secretariat of the FCTC. This issue will be discussed at INB3 after the presentation of a paper prepared by the FCTC secretariat in conjunction with UNODC.

Product Regulation and Disclosures

There are a number of potential benefits from U.S. engagement on product regulation and disclosures.

First, extending the mandate of the FDA to encompass the regulation of tobacco products will further stretch its capacity to carry out its core functions. However, international engagement by the FDA on questions of product regulation would allow it to draw on the work of the WHO, Canada, the European Community, and Norway, as well as other countries that have been working on these issues.

Second, product regulation and disclosure standards developed within the FCTC context may ultimately serve as international standards. Taking a regulatory approach that departs from such standards could increase the costs of regulation and constitute an unnecessary obstacle to international trade. In this respect, Article 2.4 of the Agreement on Technical Barriers to Trade, a World Trade Organization (WTO) agreement requires WTO members to use international standards (as defined in that agreement) unless they would be an ineffective or inappropriate means of pursuing the regulatory purpose sought. Accordingly, if the United States is to further regulate tobacco products and disclosures, it has an interest in participating in the formulation of international standards.

Reputational Consequences

The historical context within which the FCTC was concluded means that well-managed engagement by the new U.S. administration could result in a reputational payoff for the United States. Ratification of the FCTC could symbolize a clear U.S. shift from past policies that were perceived as actively promoting tobacco consumption in developing countries to a new policy of partnership aimed at minimizing tobacco consumption.

Equally, in order for U.S. ratification to produce a sustained reputational payoff, the United States will have to engage in a manner that is sensitive to the ways in which other parties view the FCTC. Most provisions of the FCTC are largely discretionary in character. Similarly, guidelines to the relevant provisions are ordinarily intended to elaborate best practices in domestic tobacco control rather than to bind the parties to a new course of action. Consequently, strong substantive provisions are used, at the expense of including enforcement mechanisms and binding approaches. Health ministries and civil society then use these international instruments in lobbying for policy change and law reform at the domestic level.

Those countries that have invested resources in developing the convention and that use it to prompt domestic and international policy change often exert significant political pressure on those members that object to the further substantive development of the FCTC. Civil society groups also seek to increase the political pressure on parties by making public (and critical) commentary of the positions put by parties.[11]

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[11] During FCTC meetings, these groups use a daily bulletin to award a symbolic "dirty ashtray" to any party that has taken an unhelpful position on the previous day.

This suggests that the United States would not reap a reputational payoff if it continued to oppose changes favoring the protection of public health or if it sought to elevate commercial interests over those of protecting public health. This type of engagement would also undermine the U.S. reputation, encourage those FCTC parties that seek to slow policy development, and could ultimately hinder international tobacco control.

Financial Implications of Ratifying the FCTC

The FCTC uses the Financial Regulations and Financial Rules of the WHO.[12] In line with these rules, the convention's budget is funded by a scaled system of assessed contributions. The maximum assessed contribution of any one state is 22 percent of the total budget. For 2010–2011, the two-year budget from which assessable contributions are determined is capped at $8,747,727, and the total budget is $12,880,000.[13] Accordingly, the maximum amount that the United States would be obligated to contribute for this two-year period would be approximately $1.9 million.

In the context of the federal excise tax on tobacco products, totalling approximately $7.5 billion in the year 2007, a U.S. budgetary contribution of $1.9 million is relatively small.[14] The potential for a protocol on illicit trade in tobacco products to increase tax collection also means that this budgetary contribution is an investment with the potential to produce high financial returns. The European Commission has impliedly recognized this potential by making a one-off extra-budgetary contribution of approximately $1.5 million to support one round of negotiations for the optional protocol on illicit trade in tobacco products.

Conclusion

If the proposed Family Smoking Prevention and Tobacco Control Act is passed into law, the United States will be in a position to quickly ratify the FCTC. Although ratification alone is unlikely to generate all the potential payoffs associated with becoming a party, ratification would leave the United States well placed to contribute to, and benefit from, ongoing processes relating to issues such as illicit tobacco trade and product regulation. In addition, a reputational payoff may follow from ratification if the United States engages in a manner that is supportive of further development of the convention. In particular, the provision of assistance to developing countries on issues such as monitoring and surveillance would be welcome.

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[12] WHO, *Financial Regulations and Financial Rules* (Geneva: WHO, 2003), http://whqlibdoc.who.int/hq/2003/WHO_CBF_2003.1.pdf.

[13] The difference between the total budget and the budget from which assessed contributions are determined reflects the intention of the parties to have $4,130,000 funded through voluntary extra-budgetary contributions.

[14] Staff of the Joint Committee on Taxation, "Modeling the Federal Revenue Effects of Proposed Changes in Cigarette Excise Taxes," October 19, 2007, JCX-101-07 http://www.house.gov/jct/x-101-07.pdf.