

Evolution of Tobacco Labeling and Packaging: International Legal Considerations and Health Governance

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Numerous national governments have recently adopted packaging and labeling legislation to curb global tobacco uptake. This coincides with the World Health Organization's 2011 World No Tobacco Day, which recognized the extraordinary progress of the Framework Convention on Tobacco Control (FCTC).

The tobacco industry has presented legal challenges to countries, including Australia, Uruguay, and the United States, for enacting legislation meeting or exceeding FCTC obligations.

We argue that national governments attempting to meet the obligations set forth in public health treaties such as the FCTC should be afforded flexibilities and protection in developing tobacco control laws and regulations, because these measures are necessary to protect public health and should be explicitly recognized in international trade and legal agreements. (*Am J Public Health*. 2013;103:e39–e43. doi:10.2105/AJPH.2012.301029)

THE 2011 WORLD NO TOBACCO

Day recognized the substantial progress of the World Health Organization's (WHO's) Framework Convention on Tobacco Control (FCTC). Yet FCTC implementation challenges remain, specifically for tobacco packaging health warnings required by article 11. Taking the recent Australian plain packaging legislation as one example, we have explored the challenges and barriers faced by national governments attempting to abide by the obligations and recommendations of the FCTC. We have argued that there is a continuing need for measures to protect populations from the scourge of tobacco and for the prioritization of health in all global policy.

Tobacco use is a global epidemic that kills approximately six million people annually.¹ The FCTC, the only international public health treaty, is a landmark in global health governance and the battle against tobacco use. Currently, 176 countries are FCTC parties, with about 20 national governments adopting or strengthening FCTC-related national tobacco legislation.² The FCTC is binding on countries that become parties to the treaty.

Tobacco accounts for almost two thirds of global noncommunicable disease, and thus a global approach to tobacco control, as emphasized by the United Nations General Assembly Special Session on noncommunicable diseases, is needed. Furthermore, smoking increases the risks of infectious diseases such as HIV/AIDS and tuberculosis and those caused by the human papilloma virus and

Helicobacter pylori, and there are substantial adverse environmental effects from tobacco growing, manufacturing, and waste disposal.^{1,3–6} This adds to economic externalities of tobacco use, which include health care costs; lost productivity, pain, and suffering; diversion of agricultural resources away from food growing; and reduced household expenditures for essential goods.^{7–10}

Compounding direct effects of smoking on the individual, approximately 600 000 nonsmokers are projected to die from second-hand smoke exposure.¹¹ Thus, binding international obligations involving multisectoral approaches are critical to alleviate the social, economic, and health burdens of tobacco use, especially for the 80% of the world's one billion tobacco users living in low- and middle-income countries.⁷

Tobacco packaging to influence marketing is a specific FCTC concern. The industry has invested significant resources to target specific consumer demographics, promote brand image, and mislead consumers regarding cigarette safety.¹² Article 11 establishes obligations and standards for packaging and health warnings, with implementation and monitoring conducted through the Conference of the Parties.¹³ The obligations, or required standards, mandate rotating health warnings covering a minimum of 30% of principal display areas (i.e., front and back of packaging).¹³ Under the FCTC, parties are encouraged to craft national laws for packaging and labeling exceeding these

standards.¹³ In fact, the FCTC recommends warnings covering at least 50% of packaging and the use of graphic displays of health consequences that are not dependent on consumer literacy.¹⁴

Although most countries include some kind of tobacco product health warning¹⁵ and adoption of FCTC recommended labeling has increased, 87 signatory countries fail to meet the FCTC's minimum obligations for labeling.¹⁶ Of 19 countries enacting recommended labeling, none are low income and only 30 mandate labeling covering at least 50% of the package.¹⁶ Indeed, the two most populous countries, China and India, have not fully complied with FCTC obligations. India does not meet minimum requirements for principal displayed areas although it includes pictorial warnings.¹⁶ China, the world's largest consumer and producer of tobacco, enacted legislation in 2009 to meet FCTC requirements but has been criticized for not including graphic content.¹⁶ As a result, China's current packaging and labeling legislation fails to meet specific FCTC requirements and may even be less effective than was prior Chinese labeling.¹⁷

The combination of limited low- and middle-income country FCTC compliance and tobacco industry challenges brought under trade agreements, intellectual property rights, and investment rules suggests that FCTC implementation will require stronger support and diligence in sustaining its effects. Because tobacco use in many developed countries is declining

yet demand and production is increasing in low- and middle-income countries, where the industry is focusing marketing efforts, low- and middle-income countries may need more technical, policy, or multinational support to implement effective labeling requirements and guidelines.

RECENT GLOBAL DEVELOPMENTS

The United States, Australia, and Uruguay have enacted tobacco labeling legislation meeting or exceeding FCTC recommendations. However, the United States, an FCTC signatory (i.e., a national government that is not bound by the treaty but has good faith obligations to refrain from acts defeating the object and purpose of it), has yet to ratify it. US law would require large graphic health warnings about smoking and second-hand smoke exposure,^{7,18} and would include a toll-free phone number to provide cessation counseling (another element of FCTC guidance).^{14,18} This is the first change in US cigarette warning labels in 25 years and would include US Food and Drug Administration monitoring.¹⁸ However, the tobacco industry has challenged US legislation on grounds of First Amendment rights of commercial free speech, and one federal court has issued a preliminary injunction that has been upheld, delaying implementation—which was originally planned for 2012—until final resolution.¹⁹ The Obama administration requested a rehearing on the decision which was recently denied. A separate, conflicting decision by a federal appellate upholding the graphic warnings requirement may consequently require the US Supreme Court to resolve the matter.²⁰

Australia's legislation on tobacco marketing exceeds FCTC

minimum obligations.²¹ The law, which was implemented December 1, 2012, and was recently upheld by the high court of Australia, requires tobacco products to be sold in plain packaging, with graphic warnings comprising 75% of the front and 90% of the back.^{21,22} It also precludes use of logos and colors, requiring all tobacco packaging to be the same color. Promotional text is limited to the brand or product name using standardized print formats.²² The law seeks to limit package-based marketing, reduce smoking desirability through unattractive packaging, and increase health warning recognition.²²

Although studies have shown that plain packaging, including large graphic health warnings, can promote smoking cessation, the industry has questioned the intervention's effectiveness in reducing uptake, using this as a legal argument against the legislation.²³ More recent studies indicate that plain packaging does have an important role in influencing brand appeal and smoking uptake or cessation and should be combined with large pictorial warnings.^{12,24,25}

Uruguay also enacted tobacco labeling and packaging rules in 2009, including a requirement for pictorial warnings, single presentation, and 80% coverage of warnings on the front and back.²⁶ However, both Australia's and Uruguay's attempts at regulating tobacco marketing have been challenged under international laws and agreements.²⁶

INDUSTRY OBJECTIONS

Although packaging and labeling legislation, such as the plain packaging requirement, has been lauded,²³ tobacco industry and trade groups have vigorously challenged it on the basis of intellectual property rights

protections and purported violations of trade and investment agreements. They also claim such packaging will encourage tobacco smuggling.²³

Philip Morris, the world's largest tobacco company, has challenged Uruguay's and Australia's laws under bilateral investment treaty (BIT) obligations. Philip Morris alleges that Uruguay's regulations violate provisions of a Switzerland–Uruguay BIT, which prohibits foreign investors from being subjected to unreasonable treatment under “fair and equitable treatment” provisions.²⁶ Philip Morris also alleges violation of the World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under these same principles and is seeking both injunctive relief and monetary damages.²⁶ Philip Morris also claims that Australia's plain packaging intervention violates a BIT between Hong Kong and Australia.²¹ In pursuing arbitration, Philip Morris, again, seeks damages for loss of business and has indicated the possibility of a billion dollar lawsuit.²⁶ Australia has indicated that in future free trade agreements it will seek to limit investor–state arbitration rights in response to this challenge.²⁶ More recently, Ukraine has also initiated a formal WTO compliant against Australia's plain packaging under the Technical Barriers to Trade Agreement, arguing that it is more restrictive than necessary to ensure public health objectives.²⁶

Industry efforts are reinforced by tobacco-producing nations relying on tobacco exports and domestic sales for a substantial portion of gross domestic product. For example, the Dominican Republic, Honduras, Mexico, Cuba, Ukraine, the Philippines, Zambia, and other members have challenged Australia's packaging legislation as violating TRIPS

and Paris Convention agreements under the WTO.²⁷ Collectively, these challenges threaten both current and future public health interventions that the FCTC requires. In fact, plain packaging legislation was previously challenged in Canada in the early 1990s.²⁶ In this case R. J. Reynolds used a North American Free Trade Agreement investment chapter to threaten to seek millions in compensation damages.²⁶ Subsequently, the Canadian supreme court invalidated the legislation supporting the intervention on the basis of violation of free speech, although at that time the FCTC and its binding obligations did not exist.²⁶

TRIPS' FLEXIBILITIES AND APPLICABILITY

In contrast to arguments against advertising restrictions, the 2001 Doha Declaration reaffirmed member state flexibility to protect public health.^{27,28} This includes a member state's right to adopt laws, regulations, and measures necessary to protect public health provided such measures are consistent with TRIPS flexibilities.²⁸ Although Doha primarily addresses access to essential medicines through the issuance of compulsory licenses, it reifies WTO member state flexibilities to assert public health priorities over intellectual property rights, although member states wishing to exercise such rights may face obstruction.²⁸ However, even as applied to medicine access, TRIPS flexibilities have been limited in their effectiveness and member states' use. Instead, these principles should be reinforced and amended, if necessary, to extend to broader public health issues and promoted for better utilization, such as for tobacco control.

Indeed, the FCTC's preamble and the Punta del Este Declaration

on implementation of the FCTC reinforce this point by reaffirming national governments' rights to "give priority . . . to protect public health."¹³ Collectively, these affirmations appear to support member states' instituting labeling and warning requirements for tobacco products, provided they are consistent with science-based evidence in support of such measures as public health interventions. Also, both current and past WTO director generals have stated that the FCTC represents an agreement to control supply and consumption of tobacco and that WTO rules and FCTC obligations are not incompatible.^{29,30} TRIPS flexibilities for public health considerations are even acknowledged by tobacco-producing member states that challenge Australia's legislation.²⁷ Further emphasizing the need for policy coherence and support of the FCTC, the United Nations Economic and Social Council recently issued a resolution calling for United Nations-wide coherence and interagency cooperation in support of global tobacco control.

In support of Australia's legislation, other FCTC parties, including New Zealand, Uruguay, and Norway, have voiced support for plain packaging; others more broadly support unilateral actions to protect public health under TRIPS.²⁷ Furthermore, the United Kingdom and New Zealand are exploring plain packaging, potentially indicating a broader multinational movement to adopt such interventions should Australia be successful against legal challenges.³¹

CURRENT GLOBAL GOVERNANCE LIMITATIONS

Challenges driven by national economic interests, application of available tools to ensure FCTC

compliance, and tobacco industry influence remain significant roadblocks to FCTC implementation. Some progress has been made with meeting article 11 packaging obligations, but other FCTC articles have moved forward with greater speed.³² For example, most parties providing WHO with implementation reports have shown progress in tobacco product tax increases, smoking bans in public places, and tobacco control research and surveillance.³² Yet fewer than one third have met all the time-bound obligations on tobacco package health warnings.³² In addition, underinvestment in tobacco control programs, waning advocacy, and repeated industry interference continue to impede FCTC implementation.

The challenge to current initiatives highlights the need for clarification and global support for interventions exceeding FCTC obligations. This "FCTC-plus" approach in support of national tobacco control legislation requires enhanced global health governance commitments to ensure policy coherence across sectors and to advocate broader application of TRIPS public health flexibilities.

International Legal Framework

The first step for ensuring effective package and labeling interventions is to specifically recognize the applicability of TRIPS public health flexibilities beyond patents and medicine access through amending or clarifying TRIPS declarations in support of tobacco control measures. A similar intervention was pursued for the implementation of TRIPS paragraph six provisions under Doha deliberations. This proposed amendment (or declaration) should specifically adopt WHO guidance on the FCTC implementation of packaging policies that clarifies that TRIPS provides trademark

owners only with the right of excluding others from using a copy-righted trademark, not the right to explicitly use the trademark.^{28,33}

Although tobacco companies argue that plain packaging is an unjustifiable encumbrance, disputes under this claim may be referred to article 8 of TRIPS, which expressly provides for member abilities to protect public health over such concerns. Hence, WHO implementation guidance supports the conclusion that "tobacco control measures that are necessary to protect public health are likely to be lawful."³³

Australia, as a WTO member, could also bring this issue directly to the TRIPS council; support its position with legal opinions, expert testimony, and scientific evidence; and join with Conference of the Parties countries to implement plain packaging recommendations. WHO, as an observer, could lend continued support to these arguments on the grounds that the legislation is necessary to protect public health and is consistent with obligations of the FCTC, as it has provided in previous council meetings. The council could then review Australian legislation and, if necessary, request additional information to determine if this FCTC requirement is in compliance with TRIPS.

Any TRIPS council clarification could provide a presumptive argument against industry legal challenges on the basis of intellectual property rights and interrelated trade obligations, especially in the context of WTO-related disputes. This would permit resources to be devoted to more direct work on tobacco control instead of to fighting industry challenges regarding TRIPS violations.

Both the FCTC and TRIPS are international binding agreements involving harmonized norms on

trade policy. If tobacco companies enter into arbitration under the International Centre for Settlement of Investment Disputes, the center should employ WTO standards and rules in decision-making. These expressly note that science-based and justifiable encumbrances to trade can be invoked to protect public health, and thus TRIPS flexibilities should be further clarified or amended as we have proposed, including having the FCTC as the governing reference in support of such a declaration.

Even if the International Centre for Settlement of Investment Disputes adjudicates in the industry's favor, no damages should result from the tobacco industry's own claims that plain packaging is not an effective public health intervention.³⁴ In addition, industry arguments that plain packaging legislation will aid tobacco smuggling are weakened because of recent agreements on a draft FCTC treaty protocol on tobacco smuggling.³⁵ This protocol would establish new rules for supply chain licensing, marking of packaging, and global track and trace systems.³⁵ National labeling and packaging legislation should also incorporate such countermeasures to argue against tobacco industry claims that cite smuggling as a reason to prevent plain packaging.

In addition, in accordance with article 30 of the 1969 United Nations Vienna Convention on the Law of Treaties, even if there was a conflict involving BIT, TRIPS, or the FCTC, the latest treaty (in the plain packaging case, this is most likely the FCTC) would prevail, provided certain conditions were met.^{28,36} On the basis of these customary laws of international treaty conflict, international dispute settlement bodies could interpret the FCTC provisions—such as article 5.3, which provides the guideline that parties should

refrain from granting incentives for tobacco investment—as prevailing.²⁸ Hence, on the basis of this hierarchy, it is crucial that future trade and investment agreements explicitly recognize public health priorities in trade disputes involving tobacco control measures (as supported by FCTC article 2.2).²⁸ Countries (e.g., Switzerland) that are only FCTC signatories, nevertheless have affirmative obligations to refrain from acts that would defeat its object and purpose under the United Nations Vienna Convention on the Law of Treaties and hence should not support BIT provisions that undermine the FCTC.³⁷

Another crucial concern regarding future challenges from the industry comes from investor rights. National governments should ensure that future trade agreements specifically exclude or provide an exemption for tobacco products and control measures as well as limit or eliminate investor–state dispute settlement provisions that enable industry claims.²⁶ Consideration of these exemptions should be part of the negotiations now underway to establish the Trans-Pacific Partnership Agreement.²⁶

FCTC-Plus Implementation

In addition to TRIPS flexibilities for tobacco control, direct promotion of the FCTC-plus interventions in two-year “revision cycles” should be explored. Given studies showing that graphic images and larger warnings are more effective than are current minimum requirements,¹⁵ the FCTC-plus implementation could include guidance to phase out minimum 30% coverage and phase in at least 50% coverage with graphic images over a prescribed period. Biennially, the World Health Assembly can reassess new tobacco control evidence and regulatory science to improve FCTC implementation.

WHO could also assist low- and middle-income countries in implementing graphic images and health messages by facilitating free licensing of its FCTC Health Warnings Database content. Although revisions to an existing treaty instrument are challenging, they are critical in ensuring that new tobacco control science is incorporated and the continued tobacco epidemic growth trajectory is addressed in the future. This proactive revision cycle would help transform the FCTC into a dynamic, living instrument, similar to suggested additions to environmental treaties and conventions.

CONCLUSIONS

Private sector challenges using intellectual property rights and trade and investment policies to counter implementation of health treaties are a major barrier to not only the FCTC’s implementation but also future binding global health agreements. Reemphasizing the importance of public health interventions through amendment and clarification of TRIPS and harmonizing international treaty obligations to explicitly support tobacco control will better ensure compliance. These efforts can transform the FCTC into a dynamic instrument and strengthen global health governance along with national governments’ capacity to fully implement the FCTC as the first WHO-originated health treaty. As smoking continues to cause millions of deaths globally, national governments must respond with consistent “health in all policies” across trade, foreign policy, and health sectors. This policy consistency is the essence of global health engagement, and tobacco control is an archetypal global health challenge that extends across national boundaries and requires binding

international agreements for effective multinational action. ■

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B. A. Liang reviewed the article for its legal and policy analysis. All authors conceptualized the study and wrote and edited the article.

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