POLICY REPORT

THE POLITICAL ECONOMY OF TOBACCO CONTROL IN BRAZIL:

Protecting Public Health in a Complex Policy Environment

Centro de Estudos sobre Tabaco e Saúde (FIOCRUZ/ENSP)
American Cancer Society

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Protecting Public Health in a Complex Policy Environment

IMAGE PROVIDED BY MARCELO MORENO, CETAB.

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Executive Summary

As Brazil and many other governments work toward developing effective public health policies, it is crucial to consider the broader economic and institutional policy-making context. This report focuses particularly on the nexus of tobacco control and international economic policies, including trade and investment. Brazil is an excellent case study because of its advanced tobacco control regime and its increasing international economic openness. The report begins with close technical examinations of the potential implications of new trade and investment agreements for Brazil's tobacco control policies and efforts. Next, it develops a more abstract discussion of the intersection and interaction of international agreements and domestic policies. In particular, we discuss how Brazil's participation in the development of the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) has both informed domestic tobacco control policies and been informed by them. As a logical extension of this discussion, we then examine two key domestic institutional dynamics that affect tobacco control and public health more deeply and broadly. First, we focus specifically on the importance of autonomous governmental institutions that promote public health, using the case of Brazil's main health surveillance and regulatory agency and its experiences with promoting tobacco control. Second, we focus on intra-governmental cooperation around tobacco control as different sectors in the government seek to generate public health policies through a national coordinating mechanism.

We investigate these lines of inquiry through surveys of existing research and official documents, and key informant interviews across all relevant sectors. The themes are germane to broader efforts to improve public health policies around the globe, particularly prevention of noncommunicable diseases (NCDs).

Implications of New Trade Agreements for Tobacco Control in Brazil

Free trade agreements (FTAs) substantially liberalize all trade between participating countries and thereby go above and beyond commitments made at the World Trade Organization (WTO). FTAs pose two risks for tobacco control that can be analyzed in the Brazilian context.

The first risk is that lowering tariffs (customs duties) may stimulate tobacco consumption by leading to lower retail prices for imported products and increasing competition among producers. Our analysis suggests that it is difficult to predict the impact of lowering tariffs on retail prices in Brazil. Some facts suggest that Brazilian producers are protected from competition by tariffs, and others suggest that tariffs play a relatively small role in the composition of the market. In this respect, a minimum price for cigarettes limits competition based on price, suggesting that existing tariffs are likely to have most impact on high-value brands.

The second risk is that FTAs may place additional legal constraints on the ability of parties to implement tobacco control measures. Contemporary FTA negotiations (albeit negotiations in which Brazil is not participating) highlight four important issues for consideration.

First, FTAs often include chapters on investment protection, which provide foreign investors, including tobacco companies, with additional legal rights. To date, Brazil has not ratified agreements providing for investor-state dispute settlement, meaning that new commitments in this area would extend the legal rights available to tobacco companies. In this context, it is recommended that Brazil maintain its current approach on investor protection. Alternatively, if Brazil does begin to pursue such agreements, the country should use models that protect policy space for regulation in the interests of public health.

Second, FTAs often include strong obligations with respect to the protection of intellectual property rights. If such obligations provide tobacco companies with a right to use trademarks, they may be problematic for tobacco packaging and labeling measures such as plain packaging. Brazil has historically been a staunch defender of flexibilities in the context of agreements governing intellectual property rights, and it is recommended that Brazil resist attempts to create positive rights permitting the use of trademarks.

Third, FTAs may include provisions governing regulatory processes that provide the tobacco industry with a forum to challenge tobacco control measures, such as with respect to cost-benefit analysis. These fora may provide a platform for the tobacco industry to influence regulatory decision making.

Finally, tobacco-specific language in trade agreements may either protect tobacco control measures or endanger them, depending on the language used.

In summary, policymakers should evaluate these legal risks in all future FTA negotiations.

Investment and Fiscal Incentives in the Brazilian Tobacco Sector

Governments use investment and fiscal incentives, such as tax holidays, to attract investment. In the tobacco context these

incentives generate savings that lower the cost of production. The law of supply and demand suggests that tobacco consumption is likely to increase if these savings are passed on to the consumer in the form of lower prices. For this reason, Guidelines to Article 5.3 of the WHO FCTC recommend that parties should not grant incentives to tobacco companies.

In Brazil, however, fiscal incentives have been offered in a number of different forms, including tax exemptions, subsidies in the form of seeds for growing other crops during the off-season, and loans to support tobacco growing. Various subsidies have been offered at both the state and federal levels. If subsidies act as a side-payment to placate growers with respect to tobacco control, they may have a positive impact on the political economy of tobacco control. Assistance for the development of alternative livelihoods provides an example of this. However, subsidies supporting manufacturing in Brazil do nothing but support the industry and strengthen its political position. Accordingly, subsidies for manufacturing should be opposed on both health and economic grounds.

Theorizing Regulatory Treaties

In late 2010, the Conference of the Parties to the WHO FCTC adopted Partial Guidelines to Articles 9 and 10 of the Convention concerning regulation of the contents of tobacco products and regulation of tobacco product disclosures. Soon thereafter, the health surveillance and regulatory agency (in Portuguese, *Agência Nacional de Vigilância Sanitária,* but hereafter ANVISA) launched a public consultation concerning a proposal to ban additives in tobacco products. This proposal and the regulation that followed would not have occurred but for adoption of the Partial Guidelines to Articles 9 and 10.

The drafting of those partial guidelines was facilitated partly because WHO FCTC parties treated it as a technical rather than political process. This technical process also provided an opportunity for parties to learn from the regulatory experiences of one another, thereby providing a platform for policy diffusion that might serve as a model more broadly in global efforts to prevent and control NCDs.

Institutional Design and Governance

Many scholars and observers of good governance argue that greater levels of agency autonomy can help to insulate decision makers from political influence and/or interference as they seek to develop rules and regulations. In theory, individuals in regulatory agencies are typically better informed and more rational and neutral in their rule-making efforts than their political peers who might be facing and/or serving competing interests. In Brazil, ANVISA has taken advantage of its high levels of statutory or *de jure* autonomy to regulate tobacco through proven policy interventions such as warning labels, restrictions on advertisement and promotion, and bans on tobacco additives and flavorings. Their strong reputation for professionalism, expertise, and promoting the public good has engendered greater *de facto* autonomy, which they leverage to develop pro-health policies. The tobacco industry recognizes the effects of the agency's actions on its bottom line and as a result has attacked its authority through both legal means and the media.

The case of ANVISA underscores the importance of creating official public health institutions that are sufficiently autonomous to be able to regulate for the broader public good. As countries consider how to move tobacco control and similar policy agendas forward, governments need to consider developing strong institutions that can regulate effectively, or they should seek to empower appropriate existing ones. Part of such empowerment, as we learn in the case of ANVISA, is legally protecting the agency's mandate. Finally, these agencies must be prepared for significant pushback from actors such as the tobacco industry and its allies who oppose reasonable public health regulatory efforts.

Intra-Governmental Cooperation – Brazil's National Coordinating Mechanism for Tobacco Control

Following the conclusion of the WHO FCTC negotiations in 2003, Luiz Inácio Lula da Silva issued a Presidential Decree of August 1, 2003, creating the National Commission for the Implementation of the WHO FCTC and its Protocols (Portuguese acronym: CONICQ). CONICQ was one of the first coordinating mechanisms in the world to include all sectors of government in an attempt to facilitate a whole-of-government approach to FCTC implementation and tobacco control policy generally. The structure of the commission was developed in order to systematize tobacco control within the government while preventing industry interference in tobacco control policy by explicitly excluding tobacco industry representation on CONICQ. CONICQ has played an important role in setting norms for government-industry interactions and has worked to establish synergies across different sectors of government. For example, the health sector has worked closely with the Ministry of Agrarian Development to develop strategies to implement Articles 17 and 18 of the FCTC.

CONICQ has also experienced a number of challenges, including conflicting policy preferences between sectors that have traditionally supported tobacco industry activity. These conflicts have been particularly salient as Brazil attempts to set new global standards for tobacco control, including a ban on tobacco additives spearheaded by ANVISA. CONICQ has a difficult task of bringing together historically divergent sectors

in order to create alignment and construct new policy initiatives that respect obligations to FCTC implementation. We analyze the strengths and challenges faced by CONICQ in this complex policy environment. In brief, we conclude that the leadership of CONICQ should continue to strengthen relationships between the sectors of government that have demonstrated commitment to FCTC implementation (e.g., Ministry of Finance and Ministry of Agrarian Development). CONICQ should also work with civil society organizations and other sectors of government to enforce the norms of government-tobacco industry interactions set out in the "transparency ordinance" (Ordinance from the Ministry of Health n. 713/2012), particularly targeting the institutions that work closely with tobacco industry representatives, including the Ministry of Agriculture and the Sectorial Chamber on Tobacco. Finally, CONICQ should continue to work with key decision makers to establish a whole-of-government policy on tobacco and tobacco control that takes into account issues of government support for tobacco growing and manufacturing, and aligns with FCTC obligations.

Introduction

Brazil has for many years been one of the highest-performing countries in the world in terms of its efforts to develop and implement tobacco control measures and programs. For example, it was one of the first countries to implement graphic warning labels on cigarette packages and to develop a comprehensive ban on tobacco additives and flavorings. The steady progress toward comprehensive tobacco control policy has been confronted by fierce resistance from the tobacco industry and its allies. This research seeks to understand and explain the dynamics of moving tobacco control efforts forward within a complex policy environment in which multiple players and shifting alliances can support or hinder the agenda.

This research effort began as an examination of how trade and investment policies might be interfering with and undermining tobacco control efforts in Brazil. Our research suggests that risks associated with trade and investment rules were not a central part of the tobacco control discourse. We do not, however, underestimate the possibility that these dynamics could play a crucial future role at the nexus of public health and economic policies; accordingly, we systematically evaluate these risks in the first two sections of this report. It became immediately clear, however, as we undertook the research process, that some of the issues surrounding how trade and investment directly intersect with tobacco control were much more immediately germane to the discussion of how to make tobacco control more successful (or sustain success) in Brazil. Moreover, we determined that many of these examinations and reflections are also widely applicable and generalizable to other countries' tobacco control and broader public health goals and struggles, which makes this research even more relevant to the global public health community.

Ultimately, much of our research was a very timely investigation of the vigorous battles in the halls of power in Brazil around the government's proposed ban on tobacco additives and flavorings. In particular, our desk review and key informant interviews consistently, and often emphatically, returned to three major themes: how international and domestic policies intersect and interact as governments seek to develop both, the role of agency autonomy in making public health policy, and the challenges of intra-governmental cooperation and coordination as governments seek to legislate and regulate challenging issues. Parts III, IV, and V of this report address these three major aspects.

This research was conducted utilizing complementary research methods and a broad collection of relevant data. To begin, we used process-tracing analysis to identify not only how existing relevant public health (especially, but not limited to tobacco control) and economic policies (particularly trade and investment) were functioning independently, but more to the point of the research, to understand and explain how they were intersecting and affecting each other. We utilized many different data sources, including the policies themselves, the supporting discussions within government (both elected and unelected bodies) and beyond it (including media and civil society), and the official economic, agricultural, and other related data that undergird them. As crucial parts of this broader comprehensive analysis, we examined these policies from legal, economic, and political perspectives, a process that was facilitated by our multidisciplinary and multinational research team. The team included experts with backgrounds in medicine, law, economics, health promotion, and political economy. After our desk review of relevant documents, we conducted two dozen face-to-face interviews with key actors at this policy intersection, including legislative members, officials from all of the key ministries (Health, External Affairs, Trade and Industry, Agriculture, Agrarian Development, and ANVISA), officials from all of the relevant intergovernmental bodies, and civil society representatives. We interviewed until our analysis reached "saturation" – the point at which we found consistency in the emerging narratives, or reasonable explanations of any of the inconsistencies, both of which we explore in this report. The interviews ranged between 45 minutes and 3.5 hours, and we had research ethics clearance from Brazil's *Comissão Nacional de Ética em Pesquisa (CONEP)* and from each of the non-Brazilian investigator's home institution's institutional review board or equivalent.

Part I – Implications of New Trade Agreements for Tobacco Control in Brazil

This section examines the implications of changes in Brazilian trade policy for tobacco control. Brazil, both in its own right and as a member of the Southern Common Market (MERCOSUR), is active in negotiation of trade agreements with a number of countries and customs unions. These negotiations include the European Union (EU), the Southern Africa Customs Union (SACU), Central America, India, and South Africa. These efforts could result in changes to Brazilian trade policy or commitments that have implications for the prevalence of tobacco consumption, as well as for the implementation of tobacco control policies, in Brazil. In this context, we examine the extent to which these negotiations pose risks to public health and how any such risks could be addressed. Our analysis is based on desk research and the field interviews described above.

This analysis is conducted against the backdrop of the WHO FCTC, which imposes obligations regarding tobacco control and includes provisions relevant to trade. In the latter respect, the preamble to the Convention notes that parties are "determined to give priority to their right to protect public health." Article 2.2 of the Convention also specifies that it does not affect the right of parties to enter into international agreements provided that such agreements are compatible with their obligations under the Convention and its protocols. The effect of this clause is that the WHO FCTC prevails over subsequent treaties to the extent of any conflict.[1]

Background

The World Trade Organization (WTO) is the central multilateral regime governing international trade. Under WTO law, WTO members have placed upper limits on tariffs (customs duties) applied to imported products, including tobacco products. Additionally, the WTO-covered agreements subject members to various rules concerning non-tariff barriers to trade such as regulatory measures.

WTO members are also permitted to enter free trade agreements (FTAs) and customs unions. FTAs are usually bilateral or regional in character and require elimination of practically all restrictive regulations of commerce (such as tariffs) between the territories involved (although some agreements go further than others).[2] In essence, FTAs require deeper trade liberalization than is the case under WTO commitments. FTAs often include rules that go beyond those found in WTO law, such as chapters governing investment protection and "TRIPS-plus" obligations, which require a higher level of intellectual property protection than is required under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is a WTO-covered agreement. FTAs may also include investment protection chapters, often permitting foreign investors to bring claims directly against governments.

Customs unions are a deeper form of economic integration than FTAs in that they involve the formation of a single customs territory between two or more states. As with free trade agreements, substantially all restrictive regulations of commerce are eliminated for trade between the territories involved. In addition, the territories of a customs union apply substantially the same regulations (such as tariffs) to the importation of goods from territories not forming a part of the union. Brazil is a member of MERCOSUR, which is an example of a customs union.

Trade agreements pose two risks for tobacco control. First, liberalizing trade by reducing tariffs removes protection from foreign competition for domestic industry and, therefore, may stimulate competition. The available evidence suggests that the opening of traditionally-closed tobacco markets can contribute to increases in prevalence of tobacco use under certain conditions, as occurred in Japan, South Korea, Taiwan, and Thailand in the 1980s and 1990s.[3] Reasons for this include lower product prices (when tariff reductions are passed on to consumers or competition is increased), more aggressive marketing by tobacco companies, and the targeting of untapped markets such as women and children.[4] In this context, by requiring parties to lower tariffs on goods originating in the territory of FTA partners, there is a risk that new FTAs could indirectly stimulate tobacco consumption (although this effect might be negated through tobacco control measures, such as increasing excise taxes on tobacco products).

Second, rules governing non-tariff barriers to trade and investor protection place limits on domestic regulatory autonomy beyond the rules of the WTO, which are focused on non-discrimination and the necessity of regulations. In other words, domestic tobacco control measures may be subject to legal challenges on the basis of commitments made in FTAs. In this context, there is a risk that expanding those rules could limit regulatory autonomy to a greater degree than is the case under existing agreements.

1. For discussion see Benn McGrady, Trade and Public Health: The WTO, Tobacco Alcohol and Diet, Cambridge University Press, (2011), pp 234-243.
2. See General Agreement on Tariffs and Trade 1994, Article XXIV:8(b) for a more detailed definition.
3. Frank Chaloupka and Adit Laixuthai, "US Trade Policy and Cigarette Smoking in Asia" NBER Working Paper Series, Working Paper 5543, (April 1996).
4. For a summary of the recent literature see Benn McGrady, Confronting the Tobacco Epidemic in a New Era of Trade and Investment Liberalization, World Health Organization, (2012); See also the discussion in McGrady, Trade and Public Health, pp 2-7.

Tobacco Tariffs and Tobacco Production in Brazil

In order to examine the risk that new tariff rate commitments might have on demand for tobacco products in Brazil, it is necessary to examine the existing commitments (bound tariff rates), actual applied tariff rates, and the composition of the Brazilian tobacco market. The analysis set out below demonstrates the difficulty of predicting what impact lowering tobacco tariffs is likely to have in Brazil.

On one hand, a number of facts suggest that Brazilian firms engaged in tobacco manufacturing are relatively protected against competition from imported products, and particularly products originating outside South America. These facts include a high MERCOSUR external tariff on manufactured tobacco products, the market dominance of Souza Cruz (a subsidiary of BAT), the strong presence of small domestic brands, and the nearly complete absence of imported products in the marketplace. In addition, a retail price floor (minimum price) limits competition based on price in the Brazilian market.

On the other hand, tobacco products originating in MERCOSUR and some other countries may enter Brazil tariff free. Multinationals such as Philip Morris (and to a lesser extent Japan Tobacco International, or JTI) also have a presence in the Brazilian market through foreign direct investment. Leaf growing in Brazil also permits companies to locate their entire production chain in the country. As such, established products enter the marketplace tariff free, thus reducing tariffs would not result in a saving to manufacturers already in the Brazilian market and subsequent price reductions on the end product. This suggests that prices would only be likely to decline as a consequence of a tariff reduction increasing the competitiveness of imported products in the Brazilian market. (Even so, with a minimum price in place, competition would only be enhanced for products sold above that minimum, such as brands in higher-value segments of the market.)

In short, it is difficult to predict what impact a tariff reduction may have on trade flows or the affordability of retail tobacco products (all other factors remaining equal). To a large extent, the impacts would depend on strategic decisions made by tobacco manufacturers, including the merits of having an integrated supply chain in Brazil and other incentives for maintaining production in Brazil.

Analysis

As mentioned above, Brazil is a member of the customs union MERCOSUR. MERCOSUR maintains a common external tariff (CET) that is applicable to goods imported from non-MERCOSUR territories. The average ad valorem MERCOSUR CET for tobacco and tobacco products ranges between 14% and 20% depending on the tariff line in question. As a general rule, tariffs levied on inputs for production of tobacco products, such as leaf, are in the vicinity of 14%, whereas tariffs on the importation of tobacco products are in the vicinity of 20% (of the wholesale value).[5] This constitutes a form of "tariff escalation" designed to incentivize production and value-added processes taking place in Brazil. Brazil's applied tariffs are in line with the MERCOSUR CET.

Brazil applies a 20% ad valorem tariff on the importation of cigarettes from the territory of WTO members. Exemptions to these duties exist for cigarettes imported from MERCOSUR (Argentina, Bolivia, Paraguay, Uruguay, and Venezuela) as well as Chile, Colombia, Cuba, Ecuador, and Peru.[6] Under these exemptions, no tariffs are levied on cigarettes imported from the countries in question, some of which are low cost producers and might compete on price were it not for the minimum price law.

In any case, the vast majority of cigarettes consumed in Brazil are also produced in Brazil. For example, it has been estimated that in 2012 less than 1% of cigarettes consumed in Brazil were imported.[7] In line with these figures, the vast majority of tobacco products consumed in Brazil are not subject to tariffs. This suggests that the retail prices of most tobacco products in the Brazilian market are unlikely to decline directly as a result of savings from reduced tariffs being passed on to consumers. However, the figures above are also consistent with the hypothesis that lowering tariffs on the importation of tobacco products would stimulate competition in Brazil by increasing the competitiveness of imports. The figures suggest that tobacco products produced in the Brazilian market are, for the most part, not competitive in foreign markets and that tariffs on imported tobacco products may be limiting competition in the Brazilian tobacco market (at least for products with retail prices above the minimum price).

However, multinational tobacco companies have invested directly in the Brazilian market. Accordingly, some major international brands are already sold in the Brazilian market or could be manufactured domestically for that market. For example, in 2012 Souza Cruz had approximately 76% of the cigarette market, and

5. Information provided on the Brazilian government website through http://www.desenvolvimento.gov.br/arquivos/dwnl_1266862939.xls and a search through the WTO Tariff Download Facility at http://tariffdata.wto.org/ReportersAndProducts.aspx. Last accessed on 20 May 2014.
6. Based upon a search of the International Trade Center Market Access Map available at http://www.macmap.org/QuickSearch/FindTariff/FindTariff aspx, last conducted 20 May 2014 (data available through 2012).
7. Cigarettes in Brazil, Euromonitor International, October 2013, table 17, p. 10.

Philip Morris Brasil held approximately 14% market share.[8] BAT and PMI also have manufacturing facilities in other MERCOSUR countries from which tobacco products may move tariff free into Brazil. This suggests that the preference to supply the Brazilian market through domestically manufactured cigarettes may be attributable to factors other than tariffs. JTI provides a possible exception to this conclusion as it has begun importing Camel and Winston brand cigarettes into Brazil (although this might be to test the market before committing to manufacturing in country).

With respect to tobacco leaf, lowering tariffs would increase the competitiveness of imported leaf. However, a number of factors suggest that this is unlikely to place significant downward pressure on retail prices of manufactured tobacco products in Brazil. These include the fact that leaf makes up a small proportion of the overall price of manufactured products and that Brazil is a major exporter of leaf (suggesting that Brazilian leaf is competitive in the global markets).

In summary, the vast majority of tobacco products consumed in Brazil are produced domestically and not subject to tariffs. Lowering tariffs would increase the competitiveness of imported products, but the preference of multinational manufacturers, such as BAT and Philip Morris, to manufacture within Brazil may be based on factors other than the tariff wall. As such, it is difficult to predict whether lowering tariffs would place downward pressure on retail prices.

Legal Risks: Non-tariff Barriers and Investor Protection

As was noted above, FTAs extend international rules that limit the regulatory autonomy of countries. In this respect, new trade agreements involving Brazil or MERCOSUR could affect Brazilian tobacco control, such as if they extend Brazilian commitments on investor protection, intellectual property protection, regulatory coherence, or tobacco more specifically. This section highlights the issues in brief and points to approaches that preserve sufficient regulatory space for sound tobacco control measures.

Investor Protection

States protect the assets of their nationals when invested abroad by agreeing to bilateral investment treaties (BITs) with other states. For example, a BIT between Australia and Hong Kong protects the assets of Australian investors in Hong Kong, and of Hong Kong investors in Australia. In light of this BIT, Philip Morris (Asia) is bringing a claim against Australia concerning plain packaging of tobacco products based upon the effect that the measure has on its Australian investment (Philip Morris Limited). These types of claims are settled through international arbitration and governed by the terms of the BIT rather than by domestic law. It is common for FTAs to include investment chapters that have similar terms and effects to BITs. Accordingly, an FTA might expand the protections available to foreign investors in Brazil.

Historically, Brazil has taken a very cautious approach to protection of foreign investment. Although Brazil has negotiated a number of BITs, including through MERCOSUR, none of those agreements has entered into force, partly because Brazil has not ratified them.[9] Accordingly, any new international commitments to protect the investments of foreign investors would extend new legal rights to those investors.

Many commentators hold out Brazil as an example of a country that has attracted large amounts of FDI in the absence of BITs. Having observed controversial and successful claims against its neighbors, Brazil is well aware of the legal risks associated with BITs and has taken a posture largely aimed at defending its policy space. However, as Brazilian firms increasingly invest abroad, incentives to enter BITs may increase and change the posture from defensive to offensive (one that seeks to protect the investments of Brazilian nationals abroad).[10]

Should this occur, certain models in recent treaties clarify the regulatory autonomy of parties to a greater degree than most BITs and thereby provide better protection for tobacco control.[11]

Intellectual Property Protection

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a WTO-covered agreement requiring WTO members to ensure minimum standards of protection for intellectual property rights. Many FTAs include commitments to protect intellectual property that go above and beyond the minimum standards required by TRIPS. This is relevant to tobacco control because packaging and labeling measures often restrict use of trademarks either directly or indirectly. In fact, claims against the implementation of plain packaging by Australia are based partly on commitments concerning trademarks under TRIPS.

In the context of future FTA negotiations, any commitments that either provide a right to use a trademark, or that constrain Brazil's ability to limit use of trademarks, could have implications for tobacco packaging and labeling measures and, in particular, plain packaging. Provisions along these lines have been introduced in other FTA negotiations. For example,

8. Ibid, table 14, p. 9.
9. See the Organization of American States website for these agreements, http://www.sice.oas.org/ctyindex/BRZ/BRZBITs_e.asp. Last accessed 25 June 2014.
10. See discussion at the International Institute for Sustainable Development's website at http://www.iisd.org/itn/2008/11/30/investment-arbitration-in-brazil-yes-or-no/. Last accessed 25 June 2014.
11. See discussion in McGrady's Confronting the Tobacco Epidemic in a New Era of Trade and Investment Liberalization, pp 64-69.

in the context of the Trans-Pacific Partnership Agreement (TPP) negotiations, early leaked US proposals suggest that the agreement could create a positive right to use names that indicate a location, such as Marlboro, as well as colors and figurative elements.[12] Such a clause could limit the ability of parties to implement plain packaging by extending the obligations established under TRIPS. A more recent leak suggests that the right would extend to words, signs, and indications, which may pose a problem for plain packaging.[13] Although Brazil is not a party to these negotiations, it would be a cause for concern if similar provisions were introduced in future Brazilian FTAs.

Brazil has been a prominent proponent of ensuring that international commitments governing intellectual property rights leave sufficient space for states to protect human health, particularly in the context of access to medicines.[14] Against this backdrop, it is reasonable to expect Brazilian authorities to be sympathetic to health concerns in light of any attempt to limit flexibility in future trade negotiations.

Regulatory Coherence

In contemporary FTA negotiations, such as the TPP and the EU-US Transatlantic Trade and Investment Partnership, the question of how to create regulatory coherence between the parties has been a significant issue. Negotiations have centered on establishing coordination mechanisms, and either harmonizing domestic regulations or recognizing diverging approaches as equivalent for regulatory purposes.[15] These proposals create at least two concerns in the tobacco control context. The first concern is that new coordination mechanisms will come with procedural obligations that strengthen the hand of industry in regulatory decision making, such as by creating transnational fora for government and industry to discuss regulation. The second concern is that harmonization might tend to push regulatory standards down rather than up because reducing regulation is often perceived as a means of facilitating trade. In this respect, there is also a concern that harmonization occurring outside of the WHO FCTC process may circumvent efforts in that forum. Because regulatory harmonization is a fast developing area of FTA negotiations, it is difficult to predict the impact on tobacco control in the abstract. Nonetheless, it is an issue to watch and one that Brazil should be aware of in future negotiations.

Tobacco-specific Language

In the context of the TPP, the United States has proposed tobacco-specific language to recognize that tobacco consumption poses a risk to health.[16] Malaysia has proposed that tobacco products be excluded completely from the scope of the agreement.[17] Although Brazil is not a party to the TPP negotiations, it is possible that tobacco-specific language may be proposed in future negotiations to which Brazil is a party. Depending on the terms, such language may mitigate concerns about the impact of new agreements on tobacco control. However, there is also a risk that tobacco-specific language will suggest that existing rules, such as those set out in WTO law, do not provide sufficient policy space for tobacco control measures. It is not possible to identify the best path forward in the abstract. As such, in future negotiations, the potential costs and benefits of tobacco-specific language should be weighed carefully.

12. Robert Stumberg, Safeguards for Tobacco Control: Options for the TPPA, 39 Am. J. L. and Med. (2013) 382.
13. Secret TPP treaty: Advanced Intellectual Property chapter for all 12 nations with negotiating positions, WikiLeaks release: November 13, 2013, Article QQ.D.14, p. 27; See also http://www.oneillinstitutetradeblog.org/plain-packaging-tobacco-trademarks-geographical-indications-tpp/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+oneill-tih+%28Trade%2C+Investment+and+Health%29.
14. Amy Nunna, Elize Da Fonseca & Sofia Gruskin. "Changing global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil," 4(2) Global Public Health, 131-149.
15. Simon Lester and Inu Barbee, "The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership,"Journal of International Economic Law (2013) 16 (4): 847-867.
16. Details of the proposal are available at the website of the Office of the United States Trade Representative: http://www.ustr.gov/about-us/press-office/fact-sheets/2013/august/fact-sheet-tobacco-and-tpp. Last accessed 25 June 2014.
17. Isra Sarntisart, "Tax Policies for Tobacco Industry in Lao PDR," Southeast Asia Tobacco Control Alliance, Bangkok, Thailand. July 2008.

Part I – Implications of New Economic Agreements – Key Findings/Recommendations

- The impact of lowering tariffs on tobacco products in Brazil is difficult to predict and depends primarily on strategic decision making by multinational manufacturers.
- Brazil has no international investment agreements in force and is a defender of flexibilities in TRIPS that protect domestic policy space.
- Establishing active platforms for discussion of tobacco control and trade may help balance economic interests with the prioritization of health.

In the negotiation of free trade agreements (FTAs), the public health community should evaluate the following:

- Whether lowering tariffs (customs duties) on tobacco or tobacco products is likely to stimulate demand for tobacco products.
- Whether additional rules governing non-tariff barriers to trade will constrain domestic regulatory autonomy in ways that affect tobacco control. These rules include:
  - Investment commitments that protect foreign investments and give foreign investors new legal rights.
  - Commitments to protect trademark rights above and beyond those set out in the law of the World Trade Organization ("TRIPS Plus").
  - Rules governing regulatory decision making that may provide the tobacco industry with a platform to resist regulation.
  - Tobacco-specific language, which could carve tobacco out of new commitments, but also affect interpretation of existing commitments.

Part II – Investment and Fiscal Incentives in the Brazilian Tobacco Sector

Governments use a variety of fiscal and non-fiscal incentives to attract investment, including tax holidays, subsidies of various types, and privileges associated with manufacturing in free zones where tax and customs laws do not apply. Governments compete with one another for investment and use these incentives to attract investors from other locations or to stimulate investment that may not otherwise occur. Investors seek incentives with a view to lowering their costs of production.

In the tobacco context, lower costs of production may be passed on to the consumer in the form of lower retail prices. The established relationship between the retail price of tobacco products and demand suggests that lower prices may increase the prevalence of tobacco use and total consumption. In turn, this is likely to increase the morbidity and mortality associated with tobacco use. With this in mind, Guidelines to Article 5.3 of the FCTC state that "[b]ecause their products are lethal, the tobacco industry should not be granted incentives to establish or run their businesses."[18]

Granting incentives to the tobacco industry can also create legal risks when it comes to tobacco regulation. For example, commitments made in the context of investment contracts between a government and an investor can constrain a government's ability to regulate the commercial activity of the investor. The partial sale of a national tobacco monopoly by Laotian authorities offers a prominent example. The investment contract in question provided the investor with a five-year profit tax holiday and fixed the excise tax rate for a 25-year period (2002 – 2026).[19] Under the contract, the investor is entitled to compensation in the event that excise taxes are increased.

Offering investment incentives may also have legal implications under investment treaties (should Brazilian agreements enter into force). For example, in a dispute between Philip Morris and Uruguay the arbitral tribunal hearing the claim relied on investment incentives offered by Uruguay to Philip Morris in finding that the tribunal had jurisdiction to hear the claim.[20] Similarly, "umbrella clauses" in investment treaties require governments to respect commitments made to investors, such as commitments made through contracts. The requirement that a state hosting investment provide fair and equitable treatment to an investor may also be relevant where a state has induced investment by offering an incentive, but has subsequently not honored that inducement.

In Brazil, investment incentives are offered at the federal, state, and municipal levels. Federal incentives, generally in the form of income tax exemptions, are offered for investment in less developed areas of the country. State governments offer incentives such as exemptions from state value-added tax, sales taxes, utility charges, and other expenses, as well as other subsidies. There are several recent examples of incentives being provided to the tobacco industry in Brazil.

Some government programs incentivize the manufacturing of tobacco products in Brazil, either for domestic consumption, export, or both. For example, FUNDOPEM is a state-based program in Rio Grande do Sul that provided Philip Morris with tax incentives to encourage construction of a new factory in Santa Cruz do Sul[21] and provided Souza Cruz with tax incentives to construct a packaging plant.[22]

Other programs subsidize the growing of tobacco leaf in Brazil, such as the provision of seeds to grow corn and beans after the tobacco harvest (in line with local laws that require crop rotation).[23] The National Bank for Economic and Social Development (BNDES) also provides loans to the agricultural sector, including tobacco growers.[24]

Tobacco growers play a significant role in political discourse around tobacco control in Brazil. This can be attributed partly to the concentrated interests growers have, to their being co-opted by manufacturers, and to the role that numerous small-scale farmers play in electoral politics. In this context, subsidies to growers (even if redistributed through other bodies) can act as a payoff (Coasian bargain) to those affected by regulation (although these effects are dubious due to the

18. World Health Organization Framework Convention on Tobacco Control, Guidelines for implementation of Article 5.3 of the WHO FCTC, Protection of Public Health Policies with respect to Tobacco Control from Commercial and other Vested Interests of the Tobacco Industry Principle 4, page 3.
19. Isra Sarntisart, "Tax Policies for Tobacco Industry in Lao PDR," Southeast Asia Tobacco Control Alliance, Bangkok, Thailand. July 2008.
20. Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (ICSID Case No.ARB/10/7) Decision on Jurisdiction, para. 165.
21. See the website of the government of Rio Grande do Sul: http://www.rs.gov.br/busca/termo=Philip%20Morris;1. Last accessed 25 June 2014.
22. See for example, Graciliano Rocha, Renúncia fiscal evita exportação do fumo, diz RS in La Folha de Sao Paulo. Available at http://www1.folha.uol.com.br/fsp/brasil/fc0806200914.htm. Last accessed 25 June 2014.
23. See Grupo Independente website: http://www.independente.com.br/player.php?cod=33985. Last accessed 25 June 2014. Notably, the tobacco industry sanctions programs promoting rotation, which it sees as a strategy to keep growers cultivating tobacco leaf.
24. Lígia Formenti, "Indústria do fumo toma R$ 336 mi do BNDES em 5 anos," Agencia Estado, Noticia, 9 September 2012. Available at http:economia.estadao.com.br/noticias/economia+geral,industria-do-fumo-toma-r-336-mi-do-bndes-em-5-anos,125965,0.htm. Last accessed 25 June 2014.

export orientation of the sector). The same can be said of efforts to support the development of alternative livelihoods for tobacco growers, which have been viewed by some as a political precondition for tobacco control in Brazil. Several key informants acknowledged that the main revenue from tobacco growing is related to exports, therefore not affected by domestic tobacco control policies. The use of tobacco growing (and growers) as an industry argument was perceived as a successful means of framing the agenda and the discussion, and acknowledged by many as a front for the industry interest.

Conversely, it is difficult to see how subsidies or incentives for manufacturing in Brazil could have any positive effect on the politics of tobacco control in Brazil. On the contrary, these subsidies and incentives strengthen the political position of tobacco manufacturers by assisting in the expansion of their operations and increasing the perception of their importance to local and national economies. These subsidies and incentives form part of Brazilian industrial policy aimed at building domestic industry, promoting value-added processes such as manufacturing, and exportation of manufactured products.

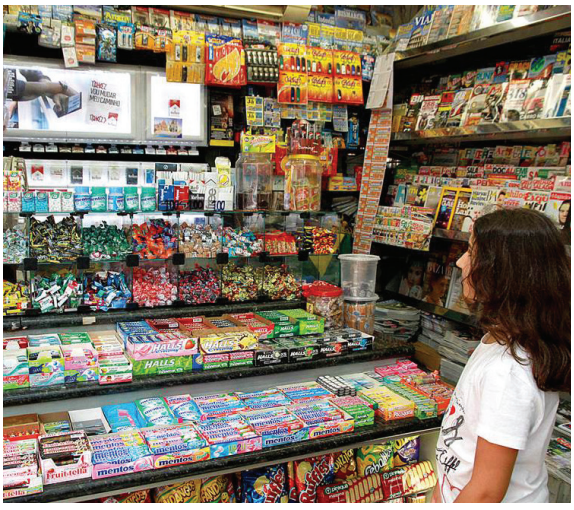
In this context, tobacco control advocates may be better off challenging subsidies for manufacturers on economic rather than health grounds. Because tobacco manufacturing is a capital- rather than labor-intensive industry, there are good grounds on which to challenge the economic benefits of these programs.

Intra-governmental cooperation around subsidies and incentives neatly highlight some of the complex dynamics around Guidelines to Article 5.3 of the WHO FCTC. Much of this cooperation – or at least attempts at it – occurs within the government's coordinating mechanism, the National Commission for the Implementation of the WHO Framework Convention on Tobacco Control and its Protocols (we use the Portuguese acronym, CONICQ). On one hand, health authorities are working to implement the WHO FCTC and its guidelines, including the investment component. On the other hand, state and national agencies with interests in agriculture and economic development are promoting tobacco production. We discuss these broader dynamics in much greater depth in Part V.

Part II – Investment Incentives and Subsidies – Key Findings/ Recommendations

In the context of investment incentives and subsidies, the tobacco control community should:

- Oppose fiscal incentives and other subsidies offered in the tobacco sector on health and economic grounds.
- Recognize that subsidies and incentives to tobacco growers may be used as a payoff for political advances in tobacco control, but that approaches designed to develop sustainable alternative livelihoods are preferable to approaches that support tobacco growing.



POINT-OF-SALE CONFUSION - CANDY OR CIGARETTES?
IMAGE PROVIDED BY ACT-BR.

Part III – Explaining the Formation and Effects of the WHO Framework Convention on Tobacco Control

In late 2010 the Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) adopted Partial Guidelines to Articles 9 and 10 of the Convention[25] concerning regulation of the contents of tobacco products and regulation of tobacco product disclosures. The partial guidelines make the recommendation that "Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products." The partial guidelines also make the recommendation that "[i]ngredients indispensable for the manufacturing of tobacco products and not linked to attractiveness should be subject to regulation according to national law."[26] The adoption of these partial guidelines, Brazil's role in their development, and their effect on Brazilian regulation contain important lessons concerning the formation of WHO FCTC guidelines and their effects on domestic regulation.

The partial guidelines were developed through an inter-governmental process. Representatives of Canada, the European Union (EU), and Norway acted as key facilitators of a working group comprised of 25 parties to the WHO FCTC, including Brazil. The key facilitators drafted partial guidelines that were submitted to the working group for comment and amendment at an October 2009 meeting. A subsequent version was submitted to parties for their comments in May 2010 and then to the Fourth Session of the Conference of the Parties (COP4) in November 2010. Criticism of the draft guidelines from some WHO FCTC parties (particularly African tobacco-growing states) was made from the floor of the COP4. In addition, the International Tobacco Growers Association (ITGA) staged a protest involving Brazilian and other tobacco growers with the aim of preventing adoption of the partial guidelines. The primary concern expressed by the ITGA and African tobacco-growing states was that restrictions on flavors and additives would have a negative effect on the livelihoods of growers of burley tobacco, a type of tobacco leaf to which most processors add ingredients.

In the lead-up to COP4, the process of developing the Partial Guidelines to Articles 9 and 10 paralleled the vigorous debate within the Brazilian government. The Department of Agriculture opposed adoption of the partial guidelines – at least in part because of concern for burley growers – and an agreement was struck through the Casa Civil (more specifically, the Chief of Staff to the Presidency) to the effect that Brazil would remain neutral on this issue at COP4 and that Brazil's health surveillance and regulatory agency, ANVISA, would not regulate additives in the event that the partial guidelines were not adopted.

Just days after adoption of the partial guidelines, the board of directors of ANVISA opened a public consultation to ban the sale of tobacco products containing additives. Following so soon after adoption of the partial guidelines, the timing of the announcement raises the question of whether the WHO FCTC had an effect on the domestic regulation. Conversely, the fact that Brazil participated as a member of the working group raises the question of what role domestic factors played in development of the WHO FCTC partial guidelines.

Our examination was guided by the following three research questions:

1. What were the conditions under which the WHO FCTC partial guidelines were successfully drafted and adopted?
2. What was the impact of the partial guidelines on Brazilian regulation?
3. What role did the WHO FCTC working group play in policy diffusion from one country to another?

These questions have important implications for policymaking. First, identifying the conditions under which WHO FCTC guidelines are drafted and adopted may help health actors to create similar conditions in the future and advance tobacco control. Second, understanding the impact of guidelines on regulation helps health actors to better evaluate the merits of developing guidelines. Third, understanding the role of working groups in policy diffusion could also help to improve institutional design not only in the tobacco control context, but also in other areas of global health.

1. The Conditions under which the Partial Guidelines were Adopted

Literature at the intersection of international law and international relations suggests a number of different, and sometimes competing, theories about why states create regimes.[27] Realist theories suggest that states create regimes in pursuit of power and, in particular, in pursuit of gains relative to other states. Rational institutional theorists suggest that states

25. The Partial Guidelines were adopted at COP4 (Punta del Este, Uruguay) in 2010, followed by the adoption of amendments to the Partial Guidelines at COP5 (Seoul, South Korea) in 2012.
26. Partial guidelines for implementation of Article 9 and 10 of the WHO FCTC, Regulation of the contents of tobacco products and regulation of tobacco product disclosures, available at http://www.who.int/fctc/guidelines/adopted/article_9and10/en/. See para. 3.1.2.2.
27. Regimes are "implicit or explicit principles, norms, rules and decision-making procedures around which actors' expectations converge in a given area of international relations." (From Stephen Krasner, Structural Causes and Regime Consequences: Regimes as Intervening Variables, 36(2) International Organization, 185-205, (Spring 1982), p. 185.

develop international regimes to solve problems of cooperation and coordination under conditions of interdependence. This neo-liberal school of thought shares some assumptions with realist theories in which both assume that states act in their own rational self-interest and pursue power. However, neo-liberals emphasize that states are concerned with absolute gains rather than gains relative to other states.[28] Liberal theory suggests that state preferences reflect the views of distinct groups within domestic society rather than the rational self-interest of a unitary state.[29] Similarly, constructivism focuses on the power of ideas and the role that structures play in influencing the preferences of states. Constructivists argue that the international system, including international organizations such as the WHO, socialize states to accept new values, norms, and perceptions of interest. Put another way, "the international system can change what states *want*."[30]

In the WHO FCTC context, collective action problems (among states) provide the grounds for a rationalist explanation of international cooperation to address those issues.[31] However, parties can implement many WHO FCTC measures unilaterally, including regulations governing additives. This raises the question of why parties would make an international legal commitment or develop guidelines on this issue. In this respect, our research suggests that the WHO FCTC may insulate domestic politics from the tobacco lobby, and that the process of negotiating the convention and guidelines may have had an educative effect for government officials and thereby shape state preferences. An additional factor to consider may lie in the structure of the convention itself, in the sense that the WHO FCTC is a framework convention designed to be supplemented by guidelines. In this respect, Article 7 required the Conference of the Parties to propose guidelines for Article 8 – 13 of the Convention.

In the Brazilian context, development of the Partial Guidelines to Articles 9 and 10 was undertaken in two stages. First, ANVISA participated as the sole delegate of the Brazilian government on the WHO FCTC working group responsible for reporting to COP4. ANVISA's position as the delegate was premised on the working group being a technical rather than a political exercise. Second, Brazil took a large delegation to COP4, with delegates from a range of agencies and ministries, for what was viewed as a political negotiation of the partial guidelines. As was negotiated at Casa Civil prior to COP4, due to disagreement between different agencies, the delegation did not play an active role in the debate around the Partial Guidelines to Articles 9 and 10 at COP4. It is not clear from our inquiries to many key actors if and how much the guidelines were discussed by relevant officials within the national coordinating body, CONICQ, and if perhaps the Casa Civil negotiation occurred because of a failure to agree in CONICQ.

Our research concerning Brazilian participation in development of the Partial Guidelines on Articles 9 and 10 revealed three key findings. First, the framing of guideline development through the working group as a technical rather than political exercise was crucial for providing ANVISA access to that process above and beyond that of other government departments with different interests. Because ANVISA was supportive of the development of the partial guidelines, as compared to other government departments, ANVISA's participation in the working group may have been significant in development of the partial guidelines.

Second, the Brazilian example shows how guidelines are developed in the context of a two-level negotiating game. Domestic regulation and domestic regulatory debates can affect the development of international instruments as states seek to embed their pre-existing regulatory approaches in the international system. Health authorities in states where regulation is under debate also look to the international level for assistance in resolving those domestic debates. In this sense, there is interplay between the domestic and international levels, with each having the potential to influence the other. In this negotiating game, different international fora provide different risks and opportunities for public health. For example, the Conference of the Parties to the WHO FCTC is a forum dominated by health interests. This might be contrasted with others such as the International Organization for Standardization (ISO), where the industry might arguably have a stronger voice.

Third, WHO FCTC parties with less developed regulations may use the process of developing international guidelines as a means of learning from the experiences of others. For example, Canadian legislation governing tobacco additives was passed in 2009[32], and Canada played a leading role in development of the Partial Guidelines to Articles 9 and 10 as a key facilitator of the working group. In this sense, the working group presented ANVISA not only with an opportunity to give technical input, or to affect domestic regulation, but also to learn from developments in the territory of other parties.

2. The Conditions under which Regimes Affect State Behavior

Our research suggests that the WHO FCTC influenced Brazilian regulation in two important ways. First, but for adoption of the

28. For discussion, see Robert Baldwin (ed.) Neorealism and Neoliberalism: The Contemporary Debate, Columbia University Press (1993).
29. See Andrew Moravcsik, "Taking Preferences Seriously: A Liberal Theory of International Politics" 51(4) International Organization, 1997, 513-553.
30. See generally, Martha Finnemore, National Interests in International Society, Cornell University Press, (1996), pp 5-6 (emphasis in original).
31. Benn McGrady, Trade and Public Health, pp 247-253; For a different rationalist account see Asif Efrat, A Theory of Internationally Regulated Goods, 32 Fordham International Law Journal, (2009) 1466-1523.
32. Bill C-32, An Act to amend the Tobacco Act (also called the "Cracking Down on Tobacco Marketing Aimed at Youth Act").

Partial Guidelines to Articles 9 and 10, the ANVISA regulation would not have been passed in the form and at the time it was passed. As was outlined above, prior to COP4, government agencies with competing views on regulation of additives in tobacco products met at Casa Civil. It was agreed that ANVISA would not regulate additives unless the partial guidelines were adopted. This is not to suggest that adoption of the partial guidelines was the sole causal influence on the regulation being passed, but adoption of the partial guidelines was one condition necessary to the passing of the domestic regulation.

This finding is significant in the broader context of the WHO FCTC. In this respect, few empirical studies demonstrate the impact of the WHO FCTC on tobacco control at the domestic level. The Convention Secretariat produces periodic global progress reports that aggregate responses by parties to the WHO FCTC reporting instrument.[33] The 2012 report showed partial implementation of the Convention along with a trend toward implementation. However, the value of these reports is limited in that the reporting instrument to which parties respond asks general questions that do not provide significant detail about the measures parties have implemented. Moreover, the reports do not provide information that contributes to our understanding of why a party has acted one way or another and what influence the WHO FCTC and its guidelines have had on decision making.

In addition to these periodic global progress reports, case studies of implementation in specific countries have appeared in the academic press, but there remain questions about the impact and value of the international legal model embodied by the WHO FCTC. More specifically, questions remain about whether parties have changed their behavior out of legal obligation, or for other reasons. In this respect, at the Fifth Session of the Conference of the Parties to the Convention, the parties requested the Convention Secretariat to prepare a report on options to assess the impact of the WHO FCTC.

Second, Brazil's participation in the working group to develop the partial guidelines had an impact on domestic regulation. The chronology of events suggests that ANVISA was preparing to issue the regulation before the partial guidelines were adopted. In this respect, the working group meetings provided an opportunity for regulators to exchange ideas and information and, in particular, for Brazil and other WHO FCTC parties to learn from Canada's experience in regulating additives. Canada's earlier partial ban on additives was instructive. ANVISA learned from the Canadian example and ultimately offered a regulatory approach that was more comprehensive in the sense that it banned menthol.

3. Regulatory Treaties as a Vehicle for Policy Diffusion

Typically, scholars have argued that policy diffusion stems largely from interaction between transnational networks of policymakers and elites. More recently, however, it has been argued that policy diffusion has democratic foundations in that politicians rely on foreign models to reassure voters.[34] The Brazilian experience illustrates how each of these arguments may also hold true in the context of global tobacco control. First, the WHO FCTC has created fora amenable to the diffusion of policies from one country to another. Second, the WHO FCTC and its guidelines may be used alongside foreign models in reassuring voters and other government departments of the legitimacy of tobacco control measures. We mainly use the development of Partial Guidelines for Articles 9 and 10 as an example here, but the broader discussion pertains to most articles in this and many other treaties and international agreements.

Transnational Networks

There is a growing body of literature on policy diffusion in the field of political science. This literature suggests that policy diffusion occurs for a variety of reasons, including competition among governments, learning from the experiences of one another, coercion, and social construction.[35] One line of argument suggests that transnational networks of officials are important to these processes of policy diffusion.[36]

Through regular meetings, the WHO FCTC has facilitated the development of a transnational network of tobacco control officials and advocates. The working group for drafting of the partial guidelines provides a particularly suitable example because it was a forum in which government officials from different parties could exchange ideas and share domestic experiences. Canada, the EU, and Norway were the key facilitators of that working group and were responsible for drafting the text proposed to the broader group. Canada had banned additives with the exception of menthol prior to elaboration of the partial guidelines and shared its experience with the working group.

In addition to collaboration between ANVISA and other governments in drafting of the Partial Guidelines on Articles 9 and 10, the history of the ANVISA regulation also points to

33. FCTC Secretariat, see http://www.who.int/fctc/reporting/summary_analysis/. Last accessed 25 June 2014.
34. Katerina Linos, The Democratic Foundations of Policy Diffusion, Oxford University Press, 2013.
35. Frank Dobbin, Beth Simmons, and Geoffrey Garrett, "The Global Diffusion of Public Policies: Social Construction, Coercion, Competition, or Learning?" 33 Annual Review of Sociology, 449-472, (2007).
36. See for example Jacqui True and Michael Mintrom, "Transnational Networks and Policy Diffusion: The Case of Gender Mainstreaming," 45(1) International Studies Quarterly, 27-57, (2001).

more direct consultation between regulators and experts from Brazil, Canada, and the United States in design and justification of the regulation. For example, officials from Health Canada presented their experience to officials from MERCOSUR countries in advance of COP4 and provided background information concerning issues such as the composition of products in the Canadian marketplace. Health experts from the United States also provided evidence on scientific issues during public hearings on the proposed regulation. The fact that the Brazilian regulation occurred after similar regulations in the United States and Canada suggests that Brazil's experience might provide an example of policy diffusion. That is, the Brazilian experience could be seen as an example of one government learning from (as distinct from copying) policies implemented by other governments.

The link between the working group and the ANVISA regulation suggests that theories of policy diffusion relating to transnational networks apply to the tobacco control context. Moreover, this extends those theories by suggesting that the WHO FCTC, through its working groups, has provided a forum that may facilitate policy diffusion through learning.

This conclusion has important implications for institutional design in the global health context. Several articles of the WHO FCTC provide for the exchange of knowledge and experience to promote implementation. As stated in Article 22 of the WHO FCTC, such cooperation shall promote the transfer of technical, scientific, and legal expertise and technology, as mutually agreed. This provision provides a broader basis for parties to share experiences and encourage the diffusion of policies from one party to another. This case study also suggests that the capacity of the WHO FCTC to influence domestic regulation is not solely driven by the convention's status as international law. Rather, tobacco control efforts benefit from the processes established for further development of the treaty, in line with theories about the power of the negotiating process more generally.[37] Finally, this case study is also relevant to broader efforts aimed at prevention and control of NCDs because it suggests that creating fora to facilitate policy diffusion may accelerate policy change at the domestic level.

Democratic Foundations

Another argument suggests that policy diffusion has democratic foundations. This argument asserts that politicians adopt foreign models to reassure and persuade voters about local policy reform.[38] In a similar way, ANVISA invoked the Canadian and US regulations as a justification for the proposal to regulate additives in Brazil. Coming as it did after the Civil House agreement, and without interministerial consensus on the merits of the regulation, the purpose of referring to Canadian and US regulations was to legitimize the argument for regulation and reassure key actors of its necessity. ANVISA even went so far as to have US health experts provide evidence at the public hearings on the basis that the US is considered to be a large and influential country, particularly on scientific questions. Similarly, the Partial Guidelines to Articles 9 and 10 of the WHO FCTC were not only used to break a political deadlock, but also to justify the product regulation in the broader domestic political debate. These important influences acknowledged, one high-ranking health official also stated that ANVISA did not have to follow the US and Canadian examples and could do what it deemed necessary.

As discussed in detail below, ANVISA is an independent regulatory agency with a regulatory power conferred by statute. ANVISA was and continues to be in an antagonistic relationship with the tobacco sector in Brazil over its role in tobacco regulation. In this context, invocation of foreign models and of the partial guidelines is more likely explained by the need to give ANVISA political cover from sectors of the government that would oppose the regulation, though ANVISA, even without this cover, remains assertive of its mandate to regulate tobacco. As such, the case study highlights the domestic political value of the development of guidelines under the WHO FCTC.

37. See American Lung Association, "What FDA Regulation of Tobacco Products Really Means" at http://www.lung.org/stop-smoking/tobaccocontrol-advocacy/federal/fda-regulates-tobacco/what-fda-regulation-of.html and Campaign for Tobacco Free Kids, "Why the FDA Should Regulate Tobacco Products," (Fact Sheet) at http://www.tobaccofreekids.org/research/factsheets/pdf/0030.pdf. Both documents last accessed 25June 2014.
38. Op cit, Linos.

Part III – Formation and Effects of the FCTC – Key Findings/ Recommendations

- The ANVISA regulation of additives in tobacco products would not have occurred but for adoption of the Partial Guidelines to Articles 9 and 10 of the WHO FCTC.
- To limit the influence of the tobacco industry, and ensure good outcomes for public health, it is important to frame WHO FCTC guideline development as a technical rather than political process.
- The technical process of developing WHO FCTC guidelines can provide a forum for learning by parties and diffusion of policies from one party to another.
- The process of developing the Partial Guidelines to Articles 9 and 10, and their role in Brazilian regulation, holds important lessons for global efforts to prevent and control NCDs. The creation of international fora comprised of states and focused on technical regulatory issues may facilitate learning, policy diffusion, and stronger regulation of risk factors for NCDs.

PUBLIC SERVICE ANNOUNCEMENT BY PROMINENT PUBLIC HEALTH NGOS IN SUPPORT OF THE BAN ON TOBACCO ADDITIVES.

Part IV – The Role of Institutional Autonomy in Health Governance

According to much of the conventional wisdom of scholars who research government agency performance, greater levels of agency autonomy can help to insulate decision makers from political influence and/or interference as they seek to develop rules and regulations. More typically, theory suggests that individuals in regulatory agencies are better informed and are more rational and neutral in their rule-making efforts than their political peers who might be facing and/or serving competing interests. Many tobacco control advocates share this conceptualization of institutional autonomy, believing that it is an important way in which to shift the political economy of tobacco control in favor of public health. In the US, for example, some major health organizations have pushed for the US Food and Drug Administration to have more independent authority to regulate tobacco.[39] We examine these propositions in the context of tobacco control in Brazil.

Before discussing the Brazilian experience, it is worth noting that scholars and institutional design experts suggest that there are two fundamental types of autonomy, *de jure* and *de facto*.[40, 41] The *de jure* autonomy of an institution derives from statute or some other legal mechanism (e.g., additional regulation). In some contrast, *de facto* autonomy is the actual amount of independence that an agency wields when it is trying to fulfill its mandate; in other words, it is related directly to the amount of resistance and/or competition that it experiences from other governmental entities as it seeks to serve the public. Nongovernmental entities can also offer resistance or competition to an agency's attempts to fulfill its mission.

Brazil's health surveillance and regulatory agency, ANVISA, created by the Brazilian Congress with Law 9782 in 1999, is the institutional entity explicitly charged with promoting and protecting the public health of Brazil's citizens, which it does by registration, surveillance, research, and regulation (and sometimes enforcement and/or "control") of products and services, which can include technologies, processes, and ingredients.[42] Specific to tobacco control, the agency plays crucial roles on significant laws and regulations such as advertising bans, some smoke-free laws, packaging and labeling restrictions, and, particularly germane to this discussion, regulating tobacco product ingredients. ANVISA is officially connected to the Ministry of Health (MOH) by a periodic management contract (discussed below). In conjunction with the Ministry of External Affairs (in Portuguese, it is commonly referred to as Itamaraty), it is also responsible for relations with intergovernmental organizations that address health surveillance issues (e.g., the World Health Organization and the World Standards Organization).[43]

Officially, within the parameters of governance in Brazil, ANVISA is an *autarquia*, which means that at least by design, it is supposed to have significant *de jure* autonomy. The statute that establishes ANVISA is specific as to a number of key institutional features that experts typically identify as crucial to greater autonomy from more overt political pressures (including from both elected officials and powerful unelected officials), including appointment process, budget, and relationship to other official institutions. First, the five ANVISA directors are appointed by the President with approval of the Senate for three-year terms, with the possibility of a one-term renewal. Experts typically argue that longer terms increase independence and that leaders of agencies need sufficient time to lead an organization effectively. The Brazilian term limits for directors are average by international standards, though a number of other major governmental institutions around the world, especially central banks, have recently chosen to implement longer terms in attempts to engender even greater independence and stability in policymaking.[44] One of the ANVISA directors is appointed and confirmed as the president-director and chairs the agency's board. Directors cannot simultaneously hold public office or private sector jobs (except public academic jobs or, oddly, law firm partnerships), thereby theoretically mitigating conflict of interest risks and seeking to professionalize their positions. Similarly, directors cannot own businesses in the health sector that are regulated by ANVISA. A director can be removed in the first 120 days of his or her initial term, but thereafter only for egregious violations such as dereliction of duty, conviction of a criminal activity, or failing to fulfill the management contract (see discussion below). These removal parameters are stiff by international standards: it is difficult for a politician to remove an ANVISA director for specious reasons, which typically bodes well for increasing agency independence.

39. See American Lung Association, "What FDA Regulation of Tobacco Products Really Means" at http://www.lung.org/stop-smoking/tobacco-control-advocacy/federal/fda-regulates-tobacco/what-fda-regulation-of.html and Campaign for Tobacco Free Kids, "Why the FDA Should Regulate Tobacco Products," (Fact Sheet) at http://www.tobaccofreekids.org/research/factsheets/pdf/0030.pdf. Both documents last accessed 25 June 2014.
40. Martino Maggetti (2010), "Legitimacy and Accountability of Independent Regulatory Agencies: A Critical Review" Living Reviews in Democracy Vol. 2.
41. Martino Maggetti (2007), "De Facto Independence After Delegation: A Fuzzy-Set Analysis." Regulation & Governance 1:271-294.
42. See particularly Articles 7 and 8 of Law 9782, which spell out the broad mandate very explicitly. Available at: http://www.planalto.gov.br/ccivil_03/leis/L9782.htm. Last accessed 26 June 2014.
43. See Martijn Groenleer (2009), The Autonomy of European Union Agencies: A Comparative Study of Institutional Development. Delft: Uitgeverij Eburon.
44. Aliança do Controle do Tabagismo/Datafolha Instituto de Pesquisas: Opiniões sobre a propaganda de cigarros no Brasil in http://actbr.org.br/uploads/conteudo/620_ACT_DATAFOLHA_propaganda.pdf . Last accessed, 2 June 2014.

Financially, ANVISA demonstrates significant independence because its budget is separated from the rest of the MOH.[45] The budget comes directly from the treasury according to what is determined by the Planning & Budget Ministry of the federal government. Two principal sources comprise the annual budget, one earmarked specifically for ANVISA and the other from the National Health Fund. The use of these funds – as long as it remains in compliance with governmental budget rules – is at the discretion of the agency. The budget is used in regular activities and goes also to municipalities and states according to the work plan prepared in collaboration with stakeholders in an annual planning meeting. This dynamic centralizes budgetary power at the federal level, giving the agency significant flexibility to affect issues within its mandate at all levels of government. Fines and fees from ANVISA's regulatory activities are collected by the treasury and are not directly allocated to the agency. By international standards, ANVISA demonstrates high levels of financial autonomy, which contributes another layer of autonomy from the MOH described below. In many countries, the health surveillance agency – if there is one – is financially a direct line item in the health ministry budget and is therefore more vulnerable to the vagaries of that ministry's internal (or external) politics. In other countries, health agencies' budgets are determined annually by the legislature, which is a relationship potentially vulnerable to capture or strong influence as private interests put pressure on legislators and/or some ideologically rigid political parties seek to interfere with these agencies' health-related mandates. In essence, in such arrangements, politics rather than expertise often guide important decisions.

The relationship between ANVISA and the Ministry of Health (MOH) is contractual. The basis of ANVISA's work is a management contract, which provides the agency with the input of the MOH and makes ANVISA directly responsible for fulfilling these obligations. When the president-director takes office, s/he has 120 days to negotiate a contract with the MOH. This contract determines the agency's goals, which are agreed upon in an annual work plan and are very specific. The goals establish targets and deadlines, and include aspects such as "to deploy health risks management actions at ports, airports, and borders outposts on 80% of health surveillance units of ANVISA" (from 2011). If ANVISA deviates from the management contract, it must submit a justification to the MOH within 60 days. If ANVISA does not submit a justification, or if the MOH does not consider the justification well-grounded, the MOH can forward to the president the request for dismissal of the directors of ANVISA. Through this dynamic, the MOH has authority over ANVISA, which can potentially mitigate the agency's autonomy to regulate. For the realization of public health goals, this dynamic between the ministry and the agency could cut in several different ways. If, for example, there were a public health-activist health minister and a laggard ANVISA board, the dynamic could enhance public health regulation by compelling the agency to be more active on public health issues. Conversely, it there were a health minister not interested in or even hostile toward public health, the minister could make the job of even the most public health-minded ANVISA directors very challenging for fulfilling genuine public health goals.

In terms of tobacco control more specifically, it is not clear how the contract might help or hinder ANVISA's relationships with other key institutions as it seeks to fulfill its tobacco control obligations. For example, there is no clarity as to how ANVISA and the MOH ensure that the contract is prepared in accordance with the goals established by CONICQ, the interministerial mechanism that is charged with coordinating tobacco control and implementing the WHO FCTC. ANVISA joined CONICQ officially only in 2012, and there is no formal mechanism for coordination of their work.[46] Within ANVISA, it is also not clear how ANVISA alone, or the Office of Tobacco Products (in 2013 named *Gerência-Geral de Produtos Derivados do Tabaco*, or GGTAB) within it, coordinates work within the broader parameters of CONICQ.

ANVISA is part of the National Health Regulation System (*Sistema Nacional de Vigilância Sanitária*, or SNVS), which has a broader mandate than ANVISA to monitor and regulate health issues at the federal, state, and municipal levels. Structurally, it is not clear how the two entities coordinate tobacco control policy. One key informant reported that the SNVS has been slow to respond to ANVISA's calls for involvement in and support of their tobacco control mandate. For example, there has been limited support for ensuring the enforcement of tobacco control laws at the local level, creating awareness of the importance of the issue, introducing enforcement strategies in health inspectors' routine, promoting capacity-building initiatives, and ensuring buy-in from state and local health authorities.

Scholars and observers have also demonstrated the importance of norms and expertise in engendering *de facto* autonomy.[47] In terms of norms, an agency can derive *de facto* autonomy from the extent to which its scope of regulation aligns with dominant societal norms. Furthermore, the appearance of expertise and impartiality of the agency to the public can also contribute to its *de facto* autonomy. These variables may affect political meddling as politicians fear being seen as behaving in

45. Brasil, Ministério do Planejamento, orçamento e gestão: Manual Técnico do Orçamento, MTO 2014 in. http://www.orcamentofederal.gov.br/informacoes-orcamentarias/manual-tecnico/MTO_2014.pdf page 153 accessed in 2 June 2014.
46. See Decree http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2012/Dsn/Dsn13274.htm.
47. See Martijn Groenleer (2009), The Autonomy of European Union Agencies: A Comparative Study of Institutional Development. Delft: Uitgeverij Eburon.

a partisan fashion with an independent agency that reflects the broader public good. In several major instances, ANVISA has utilized emerging anti-tobacco norms among the public – e.g., support for a ban on flavors in tobacco products – very effectively to press their tobacco control mandate and efforts. For example, a 2011 public opinion poll in 164 Brazilian municipalities demonstrated that 75% of respondents (65% of whom were smokers) were supportive of ANVISA's proposal to ban tobacco additives and flavorings in order to reduce products' attractiveness.[48] It is worth noting that civil society organizations were also instrumental in engendering this support with a highly visible national campaign. Finally, and not trivially, the agency has a strong presence and a reputation for professional expertise among the general public, generating consistently positive results on frequent customer opinion surveys about the public services offered by the agency.[49]

Recent Tobacco Control Successes and Challenges at ANVISA

For 15 years, ANVISA has undoubtedly been one of the key official institutions driving tobacco control in Brazil. After its establishment in 1999, which gave it statutory authority to regulate any product that posed a health risk, the agency moved quickly to affirm its authority over the regulation of tobacco products. In 1999, ANVISA mandated the regulation of tobacco products and established a corresponding fee structure for product registration (RDC 320/1999). In 2001, the agency began to regulate the tar and nicotine contents, as well as the carbon monoxide produced (RDC 46/2001). The regulation also prohibited misleading descriptors such as "mild" and "light," which was the first of this kind of prohibition in the world. Also in 2001, the agency began to regulate tobacco packaging and was the second country, after Canada, to mandate graphic health warnings (RDC 104/2001). In 2002, ANVISA further institutionalized its authority with the establishment of the Office of Tobacco Products (in Portuguese, Gerência de Produtos Derivados do Tabaco, or GPDTA, changed to Gerência-Geral de Produtos Derivados do Tabaco, or GGTAB, in 2013), through Decree 435/2002, which further sought to establish standards for and to monitor the tobacco sector.

ANVISA has spearheaded the development of a ban on tobacco additives and flavorings. According to both ANVISA and the Ministry of External Affairs, ANVISA played a key role in advising the ministry during negotiations of Partial Guidelines to FCTC Articles 9 and 10. These guidelines seek to help parties improve tobacco control through the "regulation of the contents and emissions of tobacco products and through regulation of tobacco product disclosures" (Partial Guidelines 1.1). Among the issues addressed by the guidelines are attractiveness (1.2.1.1), addictiveness (1.2.1.2), and toxicity (1.2.1.3). During this time, ANVISA was also developing its domestic policy in this area, and in 2010 ANVISA officials submitted a proposal (No. 112) for a total ban on tobacco additives and flavorings to the agency's Directors Board (DICOL).[50] This was the beginning of a series of vigorous attacks against both ANVISA and the proposal.

The tobacco industry and its allies have attacked both ANVISA's *de facto* and *de jure* autonomy, though it is arguably largely because ANVISA has taken such advantage of its *de facto* autonomy to promote tobacco control that opponents are becoming keenly aware of its existing *de jure* power. The fact that ANVISA was somewhat recently established and that tobacco is a very new product in the portfolio of the National Health Surveillance system adds to the late recognition of ANVISA's *de facto* and *de jure* power. We argue that the tobacco industry is undoubtedly aware of both kinds of power but has chosen the *de jure* strategy because it anticipates more favorable outcomes within the legal system.

While this research focuses on more recent incidents around the additives and flavorings ban, it is worth revisiting some contemporary history of blatant and vigorous outside interference in ANVISA's tobacco control efforts. Legislation 9294/1996, amended by 10167/2000, banned most tobacco advertising and all sports and cultural sponsorship, and restricted advertisements to point-of-sale. However, the government delayed the start of the sports event ban until 2003 as a concession to the tobacco industry and to many actors involved in Formula 1 (F1) auto races in Sao Paulo, who claimed that without tobacco advertising there could be no races. But in early 2003, even after ANVISA's Resolution 15 (January 17, 2003) defining advertisement of tobacco products (among other things), the industry and its allies continued to pressure the government to extend the exception, creating – as described in one news outlet – a conflict between ANVISA on one side, and, on the other side, the federal government, the city of Sao Paulo, F1 promoters, F1 teams, a TV network, and the tobacco industry.[51] Four of the five teams sponsored by tobacco companies refused to remove sponsorship (one team

48. Aliança do Controle do Tabagismo/Datafolha Instituto de Pesquisas: Opiniões sobre a propaganda de cigarros no Brasil in http://actbr.org.br/uploads/conteudo/620_ACT_DATAFOLHA_propaganda.pdf . Last accessed, 2 June 2014.
49. ANVISA Press Release, 2013, "ANVISA quer saber sua opinião sobre os serviços da Agência," available at: http://portal.anvisa.gov.br/wps/content/anvisa+portal/anvisa/sala+de+imprensa/menu+-+noticias+anos/2013+noticias/anvisa+quer+saber+sua+opiniao+sobre+os+servicos+da+agencia. Last accessed, 2 June 2014.
50. For a thorough review of the timeline around the additives ban, see Silvana Rubano Barretto Turci, Valeska Carvalho Figueiredo and Vera Luiza da Costa e Silva. 2014. "The regulation of additives and flavors on tobacco products in Brazil" Caderno Ibero-Americano de Direito Sanitário.
51. Fábio Seixas, "Governo trabalha em MP para liberar cigarro na F-1," Folha de Sao Paulo 2 April 2003. Available at: http://www1.folha.uol.com.br/fsp/esporte/fk0204200302.htm. Last accessed 26 June 2014.

– Ferrari/Marlboro – did). A few days before the race, ANVISA stated that it would enforce the law and fine any team that was racing cars with the tobacco sponsorships displayed. At the time, ANVISA director Ricardo Oliva stated that the teams were breaking a law that had been known to them for 3 years. Capitulating to the pressure, the MOH, together with the Ministry of Sports, approved Provisory Measure 10702/2003, altering the previous legislation by extending the ban on international events sponsorship to September 30, 2005. The measure also determined that broadcast of international events would have to have health warnings at the start, at the end, and every 15 minutes during the event, and gave the MOH the choice to place anti-tobacco ads in the event location. In July 2003, ANVISA issued another resolution regulating the content of the warnings to be exhibited during broadcast of international events.

In the case of the tobacco additives and flavorings ban, the board of ANVISA opened up a formal consultation process on the proposed ban in late November of 2010, though it was not required to do so. The board did so in order to address any future criticism that they were not inclusive in the process. These consultations occurred only shortly after Brazil's government participated in the discussions around the Partial Guidelines to FCTC Articles 9 and 10 at COP4, though notably, as discussed above, the delegation did not take a position.

On December 14, 2010, legislative Representative Luiz Carlos Heinze (PP-RS) proposed an official congressional project to halt ANVISA's process over the ban.[52] As of mid-2014, the project has cleared several hurdles in the legislature and remains under official consideration; regardless of this effort, ANVISA has moved forward with the ban. Concurrently, the Getulio Vargas Foundation published a study commissioned by the tobacco industry and allied groups, The Effects of the Regulation of ANVISA,[53] which predicted dire negative economic consequences from the proposed ban. The study's principal arguments were familiar to tobacco control proponents, and included the following: 1) the ban is unfounded because additives have not been found to make tobacco products more addictive or attractive, 2) additives are necessary because of the various losses of ingredients in the curing process (especially sugar); 3) consumers would look to illicit products for the flavors to which they were accustomed, and 4) ANVISA lacked the statutory authority to implement the ban. The report was roundly criticized by national and international public health experts.[54]

The tobacco industry also mounted a vigorous public campaign against the proposal, including paid advertising in major Brazilian newspapers.[55] As a result of this and related highly coordinated and well-resourced efforts, ANVISA received more than 128,000 communications by mail for consideration in the consultations. According to ANVISA, only about 10 of these communications contained distinct substantive comments and questions; the remainder were form letters generated by corporate and/or associational opponents of the ban that individuals signed and sent to the agency.

In 2011, ANVISA began to capitulate on at least one specific aspect of the proposed ban. The revised RDC now permits the re-introduction of any sugars lost from the tobacco in processing. A related legislative effort to introduce an amendment to authorize the use of menthol and clove was attached to another project of law in process at the time at the Brazilian Congress (Project of law No. 2901/11) by Representative Jerônimo Goergen (PP-RS) but this effort to undermine the ban failed.

In June 2011, the first public hearing was postponed because the original venue could not accommodate the "public" interest in the hearing. According to multiple accounts, the tobacco industry had organized groups of tobacco growers to attend the hearings to make it appear that there was widespread, passionate opposition to the ban and that it would affect their livelihoods and increase contraband.[56]

Despite these efforts by the tobacco industry, ANVISA and its public health allies continued with their efforts to move the ban through the regulatory process. In 2012, the National Public Health School (ENSP/ Fiocruz, UFRI) and the National Cancer Institute (INCA), under the MOH, presented research demonstrating that the industry uses flavors successfully to lure young people to experiment with tobacco products after which many become addicted.[57] The industry countered the report with a public relations campaign focused on the "nanny state" and "freedom of choice" arguments very familiar to tobacco control proponents around the world.

52. See PDC 3034/10 at http://www.camara.gov.br/sileg/integras/829748.pdf.
53. Fundação Getulio Vargas. 2010. FGV Projetos: estudo dos efeitos socioeconômicos da regulamentação, pela ANVISA, dos Assuntos de que tratam as Consultas Públicas 112, 117.
54. See Fundacion InterAmericana del Corazón, "No se negocio: La sociedad civil frente a las estrategieas de la industria tabaclera en América Latina." 2012. Last accessed, 20 June 2014. Available at: http://www.ficargentina.org/images/stories/biblioteca/la_salud_no_se_negocia%20_-_casos_de_estudio.pdf.
55. Ibid.
56. Johanna Noblat (2011). "Proibição da propaganda opõe indústria a medicos" Folha de São Paulo, December 6.
57. Valeska Figueiredo, Vera da Costa e Silva, Letícia Casado, Tania Cavalcante and Liz Maria de Almeida, "Use of Flavored Cigarettes Among Brazilian Adolescents: A Step Toward Nicotine Addiction." presented at the 15th World Conference on Tobacco or Health (WCTOH), March 20, 2012, Singapore.

In a dramatic development in September, 2012, and one that affirms the argument that the *de jure* power of ANVISA is under attack, Sinditabaco (the Tobacco Industries Syndicate) launched an Ordinary Collective Lawsuit in the 9th Federal Court in the Federal District to stop the ban on the basis that ANVISA did not have sufficient jurisdiction to propose and implement such a measure. In September 2012, the court granted a preliminary injunction to suspend the ban. ANVISA requested a bill of review to the Federal Court of the 1st Region to suspend the injunction, but the request was denied. ANVISA then presented remedies to the Federal Supreme Court (STF) and the Justice Supreme Court (STJ), which are both pending as of August 2014. In June of 2013, ANVISA re-presented a bill of review to the Federal Court of the 1st Region and this time, the court revoked the decision granting the injunction. Sinditabaco immediately launched an appeal, which is pending as of August 2014.

In November 2012, the National Confederation of Industry took a further major step by initiating a Direct Action of Unconstitutionality (ADI No. 4874) at the Supreme Court calling into question the constitutionality of the law that created ANVISA in 1999. In April 2013, the Attorney-General's Office and the Prosecutor's Office presented legal opinions to the STF in defense of ANVISA in the case. As of August 2014, the proceeding is awaiting trial docket in plenary.

The tobacco industry and allied groups formally requested exceptions to the ban. In August 2013, ANVISA temporarily removed 121 additives from the list of prohibited ingredients while simultaneously establishing an expert group to analyze the additives and complete a report within 12 months in the Annex of Normative Instruction (IN No. 06/2013). Civil society conceptualized this decision as a setback for the ban. Ordinance 1980/December 2013 designated the participants of the expert group who are working on a tight deadline to respond to the industry concerns.

The Future of Regulatory Authority

The counterpoint to the argument that agency autonomy improves efficacy and is good for public health is the potential that politically insulated agencies that regulate poorly, or not at all, cannot be easily motivated to change course. For example, regulatory capture may occur, whereby the regulatory agency acts in the interests of entities it is tasked with regulating rather than in the public interest. In recent years, ANVISA has demonstrated robust pro-public health preferences in the context of strong technical support from the MOH, though more varied open political support from the ministry. The recent strong and substantive reactions to the challenges to RDC 14/12 demonstrate continuing resolve to regulate tobacco additives and flavorings.

Scholars have hypothesized that the relationships among the legislature, the executive, and a specific agency are central to determining that agency's ability to regulate autonomously. Calvert et al (1989) argue that both the executive and the legislature possess some ability to veto actions on the other's part, but the greater the distance in the two actors' preferences, the greater the space of the agency to regulate more on its own. One of the key implications of this argument for ANVISA and Brazil is that the appointment process of directors is therefore particularly important in determining how the agency regulates. Each of the actors will seek appointments that best represent their preferences, and this process offers one of the best opportunities to change the status quo. Recently, the tenure of ANVISA director, Agenor Alvares, a former minister of health and staunch tobacco control proponent, ended, and the lobbying to replace him was vigorous as forces in congress and their supporters sought a new director more sympathetic to the needs of the tobacco industry. The selection process is well-known to be inherently political, even with significant media coverage of these politics.[58] This inherently political dynamic demands that, when appointments come up for new directors at ANVISA, it is critical that public health proponents – in and out of government – seek to influence the process by making certain that serious candidates are in fact favorable toward public health regulation and expressing strong appointment preferences to the appropriate decision makers, particularly in the executive branch. There have been some recent structural changes at ANVISA, and two new directors began terms in 2013 and two in 2014. It is expected that ANVISA will continue with the agency mandate of a strong commitment to tobacco control. The Director General, Dr. Dirceu Barbano, has come out forcefully in favor of tobacco control and ANVISA's mandate to regulate, which has been reassuring to the public health community.[59]

Resources

Even with strong leadership, ANVISA and its GGTAB will continue to struggle to fulfill their responsibilities and mandates because of the scope and magnitude of these tasks. First, the official registration of tobacco product brands is annual for all brands and mandatory for new brands, which are constantly introduced into the Brazilian market by the tobacco industry. Second ANVISA/GGTAB must respond to frequent requests for information and complaints filed by the tobacco industry

58. For example, see discussion of political party involvement in the process in: Andreza Matais and Débora Bergamasco, "Atraso em nomeaões deixa Anvisa desde 2012 com quórum mínimo," and "PMDB e PT retomam loteamento de cargos nas agências reguladoras," Estadão Política. 21 August 2013.
59. See interview with Dirceu Barbano, "Director da Anvisa alerta para retrocesso no setor," Brasil Econômico 8 October 2013.

against the regulatory initiatives of the agency and contesting the inspection process. Despite the existing support from other sectors of the agency, GGTAB's small team is usually overloaded with the routine activities both administrative and laboratory-related, preparing background papers to support the agency's decisions, proposing new regulatory initiatives, and preparing for and responding to public consultations, while also playing an international role in several WHO FCTC working groups and other meetings. The GGTAB is understaffed to respond to the increasing demand of regulatory actions and to attacks from the industry, given the needs for coordination of the tobacco area at the National Health Surveillance System. Despite progress in placing tobacco control within ANVISA's agenda, a gap remains in mobilizing the agency's state- and municipal-level spheres to support enforcement of the existing legislation and regulations. Ideally, surveillance and enforcement of tobacco control would be fully incorporated into the state- and municipal-level inspectors' routine, with accompanying capacity-building efforts and appropriate resource allocation.

Conclusion

There is little doubt that greater autonomy of regulatory agencies can have genuine positive effects on regulators' abilities to do their work without significant political interference. In the case of ANVISA, the *de jure* autonomy to regulate unhealthy products gave it a clear mandate to proceed with many of the core tobacco control interventions that would align Brazil's tobacco control policy with its WHO FCTC obligations. The agency then also took advantage of its *de facto* autonomy to press the level of intervention by developing some of the most cutting-edge tobacco control policies in the world, including the additives and flavorings ban.

As ANVISA has learned, however, being a bold and sophisticated regulator may increase the resistance and/or scrutiny it faces, often significantly, from many facets of society, including elected officials, other parts of government, industry, civil society, and media. At times, this resistance might be so fierce that it seems like a regulatory step backward as the agency is pressured to pull back from an initiative, or even roll back previous efforts. Perhaps worse – at least existentially, and as we have seen clearly in the case of ANVISA – some of these actors might push back on the *de jure* autonomy in an effort to affect the agency's regulatory authority and efforts more comprehensively. This pushback dynamic is not necessarily a reason for agencies to slow or stop their regulatory efforts – in fact, resistance might be healthy sign that they are doing their jobs well – but agencies do need to be mindful of this dynamic as a permanent crippling of their *de jure* autonomy will deeply affect their ability to regulate in the longer term.

Part IV – Agency Autonomy – Key Findings/Recommendations

- Public health proponents should seek high levels of *de jure* autonomy when health surveillance and/or regulatory agencies are established, including the following:
    - Independent budgets
    - Longer terms for appointed leadership
    - Delinking from congressional participation
- Health surveillance/regulatory agencies should engender *de facto* autonomy by asserting their mandate to monitor and regulate public health, and protecting from attacks on their *de jure* autonomy.
    - Agencies should keep a strong public profile predicated upon high levels of expertise and protection of the general public.
    - However, agencies should be mindful of overreach as alienating powerful constituents could also undermine their ability to engender positive public health policies.

Part V – Opportunities and Challenges of Brazil's National Coordinating Mechanism, CONICQ

For more than 35 years, health proponents have urged governments to establish and utilize intersectoral arrangements as a mechanism to address a range of public health issues. These norms were first expressed in the Declaration of Alma-Ata in 1978, most explicitly articulated in the World Health Organization (WHO) Ottawa Charter for Health Promotion in 1986, and have been firmly embedded in the WHO Framework Convention on Tobacco Control (WHO FCTC).[60,61] Article 4.4 of the FCTC urges governments to establish "comprehensive multisectoral measures and responses to reduce consumption of all tobacco products at the national, regional and international levels." Articles 5.1 and 5.2 further establish the importance of intersectoral arrangements in statements such as "each Party shall develop, implement, periodically update and review multisectoral national tobacco control strategies, plans and programmes …" and "toward this end, each Party shall … establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control." These statements encourage governments to establish centralized, intersectoral mechanisms of governance for FCTC implementation.

The immediate challenge facing governments stems from the political economy of tobacco control and the fact that supporting tobacco agriculture and production is, to a certain extent, seen as a mandated responsibility of some government ministries, agencies, and departments independently of how the tobacco production chain could have impacts on populations' health.[62] The FCTC guidelines however assert, "there is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests." While an intersectoral commission can bring an advantage of enabling a single articulated position on tobacco control policies among the different sectors of the government, intersectoral mechanisms must navigate and work to transcend the conflicting mandates of different ministries. Brazil is one of the first countries to establish a distinct intersectoral national coordinating mechanism to implement the provisions of the FCTC. The following section analyzes the establishment and operation of this intersectoral commission, CONICQ, beginning with the establishment of its predecessor, the National Commission for the Control of Tobacco Use (CNCT) in 1999. The section begins with a brief overview of the history, structure, and strengths of CONICQ and follows with an analysis of some of the salient challenges that CONICQ has faced in carrying out its mandated objectives. Finally we will discuss the lessons that can be applied to the future work of the commission and future coordinating mechanisms.

CONICQ: Structure and History

The National Commission for the Control of Tobacco Use (CNCT) was established by Presidential Decree n.3136/1999. The purpose of CNCT was to prepare for and facilitate Brazil's involvement in the negotiation of the FCTC, which itself began in 1999. The commission was chaired by the Ministry of Health and included representatives from seven ministries[63] until the addition of an eighth, the Ministry of Agrarian Development, in 2001. The National Cancer Institute (INCA) served as the secretary of the commission. The commission advised the Casa Civil in the development of Brazil's position during the FCTC negotiations. Members of the CNCT attended the Intergovernmental Negotiating Body (INB) sessions during the negotiation of the FCTC.

Following the conclusion of the FCTC negotiations in 2003, Luiz Inácio Lula da Silva issued a Presidential Decree of August 1, 2003, creating the National Commission for the Implementation of the WHO Framework Convention on Tobacco Control and its Protocols (CONICQ). The Ministry of Health, in Ordinance n.1662 of August 26, 2003, ensures that the different ministries appoint representatives to the commission. CONICQ is chaired by the minister of health and, according to Presidential Decree of July 14, 2010, must be integrated by a representative (and a substitute) from each of the following ministries: Health; External Affairs; Agriculture, Food and Rural Affairs; Agrarian Development; Finance; Justice; Labor and Employment; Education; Environment; Science and Technology; Communications; Development, Industry and Trade; and Planning, Budget and Management; as well as INCA, which plays the role of executive secretary. According to the ordinance that regulates the commission, each minister nominates one member and one substitute to serve on CONICQ. An exception is made for the Ministry of Health, which has two representatives (one from INCA and one from AISA - Office of International Health Affairs) and two substitutes (also one from INCA and one from AISA), and lately a representative from Brazil's health surveillance and regulatory agency, ANVISA. The representative from INCA

60. WHO, Ottawa Charter for Health Promotion.
61. Declaration of Alma-Ata.
62. Jeffrey Drope and Raphael Lencucha (2014) "Tobacco Control and Trade Policy: Proactive Strategies for Integrating Policy Norms" Journal of Public Health Policy 34; Jeffrey Drope and Raphael Lencucha, "Evolving Norms at the Intersection of Health and Trade" Journal of Health Policy, Politics and Law 39, 3.
63. Ministry of External Affairs, Ministry of Finance, Ministry of Agriculture and Supply, Ministry of Justice, Ministry of Education, Ministry of Labor and Employment, Ministry of Development, Industry and Trade.

both represents the Ministry Health and plays the role of executive secretary of CONICQ. The structure and authority of CONICQ has created opportunities to implement the provisions of the FCTC across all sectors of government. As might be anticipated, however, the same structure has created unique challenges for those seeking maximum alignment between the international obligations set forth in the FCTC and Brazil's domestic tobacco control. The following section analyzes the strengths of CONICQ in its present form.

CONICQ: Strengths

The push for whole-of-government (WoG) approaches to health policy formulation, implementation, and enforcement emerged within a context where governments largely functioned within departmental silos. This context of departmentalism was and is seen as a barrier to addressing health issues that cut across ministries and sectors and thus require interventions that include many sectors. Tobacco control is one such issue that requires intervention not just within and by the Ministry of Health but also by ministries of agriculture, industry, finance, trade, and others. The principal claim by advocates of WoG is that intersectoral institutional arrangements that bring together different sectors of government can foster more coherent public policy. For example, in an analysis of tobacco control governance in Brazil during and after FCTC negotiations, Lee and colleagues (2010, p. 3) state that "this Commission (CNCT), including all pertinent stakeholders, ensured that tobacco control was embodied in consistent policies throughout government and not only as a health ministry issue."[64] In order to realize the potential benefits of intersectoral governance mechanisms, a need remains for more empirical analysis of how such approaches are carried out in practice. Before we discuss the challenges faced by CONICQ in carrying out its function, we discuss some of the strengths of this arrangement.

The Presidential Mandate Establishing CONICQ

Often, WoG approaches are ad hoc (i.e., responding to a temporary problem) or voluntary. A major strength of CONICQ is that it is mandated by a presidential decree. Because the highest level of government establishes CONICQ, the commission has legitimacy, public presence, and permanence. One key informant working with CONICQ noted that "it was very difficult not to support us (CONICQ), since we had evidence … we have FCTC commitment … and CONICQ was created as a directive from the President." In other words the fact that the President has mandated the establishment of CONICQ has contributed to its legitimacy across sectors, where member ministries cannot ignore the existence of the commission on the basis that it is a Ministry of Health initiative or other health department directive. The WoG structure is established and supported by the highest level of government.

Potential for Policy Coherence

The structure of CONICQ, including its composition and leadership, has provided the Ministry of Health and related health agencies the opportunity to forge alliances and coordinate policy with other ministries.[65] CONICQ has a broad and encompassing mandate to promote the development, implementation, and evaluation of strategies, plans, and programs, as well as policies and legislation, and other measures, for compliance with the FCTC obligations. CONICQ is also responsible for representing the Brazilian government at conferences of parties of the FCTC, including working and study groups and sessions relating to protocols. This explicit mandate to connect domestic policy with the FCTC provides CONICQ with a unique opportunity to continuously shape and align domestic activities with international commitments, as well as contributing to the development of international standards. Our findings suggest that the leadership role of the Ministry of Health within CONICQ has assisted it to identify and strengthen alliances with other ministries. For example, through CONICQ, the Ministry of Health and the Ministry of Agrarian Development have developed a working relationship and have cooperated on issues pertaining to Articles 17 and 18 (economically viable alternative activities). In fact, the coordinator of the executive secretariat of CONICQ and a representative from the Ministry of Agrarian Development authored a joint statement in a prominent tobacco control journal on behalf of CONICQ defending the representation of numerous sectors on Brazil's delegation to COP4 in Uruguay.[66] One of the members of CONICQ noted that its existence has helped elicit support from the Ministry of Finance, who was initially opposed to the issue of tobacco taxation. This individual noted, "At the very beginning we had very strong debate with the Ministry of Finance they were not supportive of raising taxes but … today, the Ministry of Finance is one of the most active advocates of FCTC." CONICQ has served as a forum where debates between sectors can take place. Although this space has not always resulted in the alignment of policy perspectives across the different sectors or the establishment of alliances between ministries, evidence suggests that in some cases it has.

Potential for Reducing Industry Influence

One of the reasons for the creation of the predecessor to CONICQ was to protect tobacco control policies from undue

64. Kelley Lee, Luiz Carlos Chagas, and Thomas Novotny, (2010) "Brazil and the Framework Convention on Tobacco Control." PLoS Medicine 7, 4.
65. This structural strength has also served as a limitation. We will discuss this limitation in the following section.
66. CONICQ, "Brazil's COP4 Delegation Disagrees with the Conclusions of the Research Paper 'Tobacco Industry's Fight ITGA FCTC Implementation in the Uruguay Negotiations.'"

interference of the tobacco industry. The commission worked toward this end by consolidating tobacco control within an intersectoral body. It was thought that the different ministries would be held to account for their positions on tobacco control by mandating that they work together to develop common positions on tobacco control. This structure was meant to insulate tobacco control from pro-industry preferences by orienting the commission toward health objectives and holding other sectors of government to account in light of this orientation. The commission also attempted to protect tobacco control from direct industry influence by excluding tobacco industry representatives from serving on it. The structure of CONICQ has followed the structure of the negotiation commission; the dynamic of entrenched departmentalism has increased with the creation of a Sectorial Chamber of Tobacco's Productive Chain in the Ministry of Agriculture in 2003/04. Some informants suggested that the Sectorial Chamber was established as a response to CONICQ, as a means to protect and promote the pro-industry interests that CONICQ is designed to exclude.

CONICQ: Challenges

Despite its various strengths, CONICQ has and continues to face three salient challenges: 1) internal conflicts between members, 2) the prompting of institutional responses within government to protect tobacco industry interests, and 3) the exclusion of civil society organizations. We discuss these three challenges below.

Internal Conflicts

Despite the executive role that CONICQ is meant to serve, our findings suggest that the commission mainly serves and is seen as an advisory body to the cabinet. Given the *de facto* advisory capacity of CONICQ we found that much of the work to establish stronger tobacco control measures was carried out by individual departments and agencies, acting outside of the scope of CONICQ. For example, ANVISA is a member of CONICQ, but, after COP4, largely acted independently of the commission to establish the ban on tobacco additives. This initiative has been perhaps the most dramatic example of how an individual agency has acted autonomously within its mandate to strengthen tobacco control in Brazil. The structure of CONICQ is best characterized as an arrangement of semi-autonomous entities, each engaging in and with CONICQ as a forum to develop common positions on tobacco control. This structure creates different degrees of conflict within CONICQ. One challenge within CONICQ has been the periodic lack of consensus about policy problems and solutions. For example, some members within the commission, such as those from the Ministry of Agriculture, were strongly opposed to an additives ban. This lack of consensus can create what one key informant called an "impasse" within the commission over certain issues. When consensus is lacking on major policy issues within CONICQ, the weight of the commission is lessened in its influence on the decision-making arms of government. It is worth noting that it would be unrealistic to assume that CONICQ could serve as a panacea to eliminate opposition to tobacco control. Brazil is a difficult context for tobacco control given the strong industry presence. It is in this context that the challenges experienced by CONICQ must be situated. For example, despite vehement opposition, Brazil has been able to establish one of the world's strongest measures for tobacco product packaging and labeling.[67]

As noted above, although CONICQ has been an important forum to shape the ideational or normative aspect of tobacco control in Brazil, our findings also point to the challenge of differing interests and perspectives. One informant from the Department of Trade noted, "[Y]ou can expect that different ministries will represent different points of view … until the Federal Government has a position, you can have this kind of debate." However, our findings suggest that for difficult policy problems it is challenging for members of CONICQ to reach consensus. Intersectoral deliberation is a challenge even on less controversial issues, as each sector comes with a particular perspective on policy and this perspective contributes to differing preferences. One informant with a long history in multiple aspects of tobacco control suggested that this impasse has created certain situations in which CONICQ has difficulty developing strong arguments for strengthening tobacco control and is unable to speak to decision makers as one unified entity. This informant stated, "[I]t's a difficult situation because the ministry and the secretary of health don't move, they are active at a lower level but it doesn't go up because of this institutional thing (CONICQ) and I think the way to reverse that is with good arguments – no money, no power – just arguments." Another informant – a former high-ranking federal health official – shared the same perspective suggesting that "I think … CONICQ has no decision-making power, so it plays a role, but not an important role, it does not fulfill the main role it has … because even in CONICQ we have agencies whose representatives are against CONICQ, against tobacco control policy."

We also found that, beyond neutral impasse, overt antagonism exists among some members of CONICQ. This antagonism stems partly from inherent differences in mandates across the sectors of government. Our findings suggest that these differences often create a context of mistrust between members of CONICQ. For example, one representative serving on the commission noted that they felt they should not discuss how Brazil should respond to the various trade and investment challenges to the tobacco control measures of different

67. ANVISA, Re Solution - RDC No 335, Dated 21 November 2003.

countries: "We have discussed this in the working group on legal matters with the attorney general. We need to take this matter for them to study … I think the strategic move is not to discuss it so frontally within CONICQ." Another informant from the Ministry of Agrarian Development noted that, beyond their ministry, the only members supporting tobacco control within CONICQ are Health and External Affairs, and that "all others don't support" it. Of course, support is often a matter of perspective: for example, several other informants involved with CONICQ indicated that the Ministry of Finance was generally supportive of tobacco control.

The challenge of internal conflict is one that can have different implications for the policy-making process. If all decisions pertaining to tobacco control are to be derived from the consensus-based positions of CONICQ, then it is reasonable to assume that CONICQ will not have power to shape the tobacco control agenda. However, CONICQ can also be viewed as a consensus-building entity for an issue that is intimately tied to powerful private industry interests. CONICQ, as a forum for policy debate, can strive for consensus among its members but will likely not be able to generate uniformly agreed upon pro-health positions, given that certain sectors of government serve to protect and promote the commercial activity of the tobacco industry. From the latter perspective, CONICQ can continue to establish norms of government-industry interaction and can work to denormalize the legitimacy of the tobacco industry as a stakeholder. It seems that CONICQ has recognized this role as evidenced by the recent establishment of a "transparency ordinance" in 2012. This ordinance, Ordinance from the Ministry of Health n. 713/2012, establishes ethical guidelines for CONICQ functioning in accordance with Article 5.3 of the FCTC. The ordinance sets forth guidelines for all sectors of government pertaining to interactions between government and the tobacco industry, conflicts of interest, receiving gifts and presents, and industry sponsorship of events.

Institutional Reaction

According to key informants from the Ministry of Agriculture, the ministry established a similar intersectoral body called the Sectorial Chamber on Tobacco as a response to CONICQ. According to one interviewee, "the Sectorial Chamber was created to bring together the actors of the (supply) chain such as producers, industry, government and industry workers." More than twenty chambers within the Ministry of Agriculture deal with very specific issues, making it difficult to substantiate that the Sectorial Chamber on Tobacco was truly a direct response to CONICQ. However, it is noteworthy that this chamber now has implications for the functioning of CONICQ given that both bodies share a common membership.

One informant suggested that the Sectorial Chamber on Tobacco works to protect the commercial interests of the tobacco sector and is politically stronger than CONICQ. As noted earlier, there is a distinction in the agricultural sector between the Ministry of Agriculture, the chamber, and the Ministry of Agrarian Development. Where the chamber and the Ministry of Agriculture protect and promote commercial interests of the industry, the Ministry of Agrarian Development is concerned with the livelihoods of farmers. The tobacco industry is represented on the chamber. Although it is difficult to establish a causal link from CONICQ to the chamber, it is plausible that this link exists. This plausibility stems from the ongoing efforts of the chamber and its constituents to challenge Brazil's efforts to establish more stringent tobacco control measures such as ANVISA's additives ban. There appear to be structural challenges for CONICQ given the different policy objectives of CONICQ and the chamber, and the fact that members of the chamber are represented within CONICQ. This suggests that entrenched commercial interests may inadvertently be granted access to a primary forum where tobacco control policy is discussed, and it is possible that this common membership across CONICQ and the chamber may create barriers to CONICQ's ability to serve as the epicenter of tobacco control in Brazil. This common membership may also reinforce an atmosphere of mistrust among members of CONICQ during deliberations if tobacco control proponents believe that the information they share in the CONICQ forum will be shared with tobacco industry representatives during the meetings of the Sectorial Chamber on Tobacco.

Exclusion of Civil Society Organizations

CONICQ was created as a governmental body with exclusive membership to government representatives. This decision was intended to exclude industry representatives from the functioning of the commission, thus insulating CONICQ from direct industry influence. CONICQ has the latitude to invite civil society representatives to observe their meetings, though thus far invitations have been extended to civil society only for specific presentations. Otherwise, there has been no official involvement, and when civil society representatives have presented on key topics at meetings, they have not been permitted to stay beyond their presentation. In theory, the major tobacco control organization, *Aliana de Controle do Tabagismo* (ACT)-Brazil, is a member of working groups for legal issues and for Articles 17 and 18, but as of August 2014, there have not been any official meetings. As pro-health/anti-tobacco civil society organizations continue to gain strength in Brazil, particularly under the umbrella of the Brazil Tobacco Control Alliance, there may be benefits to including civil society representatives as formal members of CONICQ. Given that CONICQ is made up of semi-autonomous sectors of

government, the possibility of continued informal relationships and partnerships between individual ministries, departments and agencies, and civil society remains. Whether the goals of CONICQ are better served by having civil society represented on the commission is something for future consideration. The blanket exclusion of nongovernment representatives simplifies the objective of preventing direct industry influence within CONICQ. However, the exclusion of health-based civil society organizations may also be a missed opportunity to strengthen the work of the commission.

Conclusion

CONICQ has played a pivotal role in advancing Brazil's positions at the Conference of the Parties and through involvement in working groups that, in some cases, involved being key facilitators on various guidelines, all of which in turn strengthened its position to articulate domestic policy. Brazil has been a key facilitator for Article 5.3 guidelines and remains a key facilitator for the development of Partial Guidelines to Articles 9 and 10, and Articles 17 and 18 guidelines, despite an ongoing internal struggle on the best strategy to provide alternative sustainable activities for tobacco growers. CONICQ has served to establish norms for government-industry interactions that cut across all sectors of government. Another result of CONICQ has been improved coherence in favor of tobacco control from sectors that in the past have opposed certain tobacco control measures, such as the Ministry of Finance. In fact, through CONICQ, as one interviewee who had represented their ministry on the commission noted, "At the very beginning we had very strong debates with the Ministry of Finance they are not supportive of raising taxes … Today, the Ministry of Finance is one of the most active advocates of FCTC [and tobacco control]."

Whole-of-government approaches to tobacco control hold great potential to establish policy alignment and coherence within governments. CONICQ is an important institutional arrangement to serve this purpose. CONICQ and its predecessor have served to strengthen the FCTC proper and continue to contribute to the establishment of implementation guidelines. This constructive relationship appears to have forged a reciprocal relationship between the international standards of the FCTC and the domestic tobacco control policy of Brazil. The broad inclusion of various ministries, departments, and agencies points to the potential of CONICQ to create tobacco control measures that are not only aligned with but also supported by the different sectors of government. We found that, in addition to these strengths, CONICQ continues to face important challenges applicable to other countries that are implementing Article 5.2 of the FCTC. CONICQ has worked to establish ethical guidelines that are meant to guide the members of the commission in their interaction with the tobacco industry (Article 5.3 of the FCTC). This "transparency ordinance" was approved in April of 2012 and is an important step in CONICQ's norm-setting function. Despite such initiatives, CONICQ is faced with a difficult situation where some of its members have direct ties with the tobacco industry and are tasked with the protection and promotion of industry interests. Although in principle broad inclusion is lauded as an objective of WoG approaches to healthy public policy, this case demonstrates the inherent challenges of such institutional arrangements. In order to move forward on tobacco control, such institutional designs must be critically assessed to determine to what extent the structure of such arrangements facilitates the intended objectives to promote and foster tobacco control. Ongoing assessment can identify what sort of changes, such as introducing civil society representation on the commission, can be made to ensure that CONICQ is optimally serving its purpose of FCTC implementation. National coordinating mechanisms are crucial for the system-wide implementation of FCTC provisions. The more lessons that can be systematically generated from the ongoing functioning of mechanisms like CONICQ, the better governments will be able to establish optimal arrangements to achieve optimal health outcomes.

Part V – Opportunities and Challenges of CONICQ – Key Findings/Recommendations

- The leadership of CONICQ should continue to strengthen relationships between the sectors of government that have demonstrated commitment to FCTC implementation (e.g., Ministry of Finance and Ministry of Agrarian Development).
- CONICQ should work with civil society organizations and other sectors of government to enforce the norms of government-tobacco industry interactions set out in the "transparency ordinance" (Ordinance from the Ministry of Health n. 713/2012).
    - This work should particularly target those ministries, such as the Ministry of Agriculture, who work closely with tobacco industry representatives, particularly the Sectorial Chamber on Tobacco.
- CONICQ should continue to work with key decision makers to establish a whole-of-government policy on tobacco and tobacco control that takes into account issues of government support for tobacco growing and manufacturing, and aligns with FCTC obligations.

Conclusion

It is difficult to sum up briefly and deftly the broad complexities at the nexus of public health and economic policymaking in Brazil (or anywhere else for that matter). However, some poignant lessons can be learned from Brazil's experiences that might help Brazil and many other countries to move forward with sustaining effective public health policy, while also integrating it effectively with economic policy goals. First, in terms of ongoing or potential threats to public health from participation in international trade and investment agreements, it is clear that information about new agreements and ongoing international litigation is vital to collect and understand in order to stay ahead of industry efforts to use international rules to undermine public health efforts. With so much recent activity around tobacco control in international economic agreements, it would be wise to remain vigilant of the myriad of potential issues. This is clearly a lesson for all countries, as considerable uncertainty exists as to how we, as a global community, seek to integrate different policy goals that might sometimes conflict. The issues outlined in this report can serve as a partial guide to considering these issues in other similar contexts.

Second, this research demonstrates that the interaction between international and domestic policymaking is highly consequential for governments, and more specifically that each level affects the other deeply and meaningfully. In the case of tobacco control, Brazil has not only played a vital role in the development of the FCTC, but its own domestic experiences with tobacco control have shaped the nature of this influence. At the same time, Brazil uses the FCTC strategically, substantively, and legally in the continued development of its domestic tobacco control policies. Any FCTC party is likely to experience some of this dynamic. Countries with highly developed policies will have experiences more similar to Brazil's, while countries just beginning to develop their tobacco control policies might consider how helpful the FCTC can be in terms of moving toward their domestic goals.

Third, Brazil's experiences with ANVISA suggest that the structure of the institutions charged with making public health policies and regulations is consequential. In particular, the ability of these institutions to make policy and regulation that is relatively free from political meddling is vitally important. We are not suggesting that there should not be regular political input into the regulatory process, but we are suggesting that relatively independent, highly professionalized, and expert governmental agencies are better poised, in most cases, in their efforts to make sound regulation for the public good, and to filter out poorly informed or pernicious efforts motivated most by political gain. There is plenty of scope for elected officials to affect regulation through channels that are transparent and provide for better accountability. In the specific scenario discussed above, ANVISA and its supporters should fight vigorously to protect its statutory autonomy, and ANVISA should continue to utilize this autonomy to regulate tobacco in innovative and tough ways that promote public health.

Finally, the narrative around CONICQ is very instructive for countries as they seek to regulate in areas that are clearly multisectoral. For all of its challenges, CONICQ has proven to be a positive force for public health change in Brazil. Of course, reconciling multiple and often conflicting viewpoints is very difficult, and made more challenging in the scenario of tobacco control by a powerful industry and government bodies that tend to support it. While of late many actors note gridlock or worse, we believe that an inclusive intersectoral mechanism is better to have than not. At worst, currently, there is still a place for many actors to get together and discuss the issues and place on the record their preferences and the reasons for their preferences. Better yet, it appears that actors continue to have opportunities to learn from others and in some cases to modify their positions that then lead to improved public health policymaking. Once again, every country in the world encounters these challenges across many policy areas, and every party to the FCTC is compelled by Article 5.2(a) to address it directly in the tobacco control context, so the lessons here are germane to many.

In sum, the narratives in this report reveal clearly that the nexus of public health and economic policymaking in Brazil is lively and contentious. Fortunately, many innovative individuals and groups are striving to navigate these complexities in new ways that produce improved policies for the citizens of Brazil. There is no panacea to any of these challenges, but the deeper understandings that we seek to develop here should help to guide those interested in positive change.

Acronyms

ACT	*Alianza de Controle do Tabagismo*
ADI	*Ação Direta de Inconstitucionalidade* (Direct Act of Unconstitutionality)
AISA	Office of International Health Affairs, Ministry of Health (Brazil)
ANVISA	*Agência Nacional de Vigilância Sanitária* (National Health Surveillance and Regulatory Agency)
BAT	British American Tobacco
BIT	bilateral investment treaty
BNDES	National Bank for Economic and Social Development
CET	common external teriff
CNCT	National Commission for the Control of Tobacco Use
CONEP	*Comissão Nacional de* Ética *em Pesquisa* (National Research Ethics Commission)
CONICQ	Portuguese acronym for: National Commission for the Implementation of the WHO FCTC and its Protocols
COP4	Fourth Session of the Conference of the Parties (FCTC)
ENSP	National Public Health School (Rio de Janeiro)
EU	European Union
F1	Formula 1
FDI	foreign direct investment
FTA	free trade agreement
FUNDOPEM	state-based tax incentive program in Rio Grande do Sul
GGTAB	*Gerência-Geral de Produtos Derivados do Tabaco* (Office of Tobacco Products, replaced GPDTA in 2013)
GPDTA	*Gerência de Produtos Derivados do Tabaco* (Office of Tobacco Products)
INB	Intergovernmental Negotiating Body
INCA	National Cancer Institute of Brazil
ISO	International Organization for Standardization
ITGA	International Tobacco Growers Association
JTI	Japan Tobacco International
MERCOSUR	Southern Common Market (or Common Market of the South)
MOH	Ministry of Health
NCD	noncommunicable disease
PMI	Phillip Morris International
PP-RS	*Partido Progressista do Rio Grande do Sul* (Progressive Party of Rio Grande do Sul)
RDC	*Resolução da Directoria Colegiada* (Board Resolution)
SACU	Southern Africa Customers Union
SNVS	*Sistema Nacional de Vigilância Sanitária* (National Health Regulation System)
STF	Supreme Federal Court
STJ	Supreme Court of Justice
TPP	Trans-Pacific Partnership Agreement
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UFRJ	*Universidade Federal do Rio de Janeiro* (Federal University of Rio de Janeiro)
WHO	World Health Organization
WHO FCTC	World Health Organization's Framework Convention on Tobacco Control
WoG	whole-of-government
WTO	World Trade Organization

Notes

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