ARBITRATION UNDER THE
RULES OF THE INTERNATIONAL CENTRE
FOR SETTLEMENT OF INVESTMENT DISPUTES

PHILIP MORRIS BRANDS SÀRL

PHILIP MORRIS PRODUCTS S.A.
AND
ABAL HERMANOS S.A.
CLAIMANTS

V.

ORIENTAL REPUBLIC OF URUGUAY
RESPONDENT

ICSID Case No. ARB/10/7

WRITTEN SUBMISSION (AMICUS CURIAE BRIEF) BY THE PAN AMERICAN HEALTH ORGANIZATION

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A. INTRODUCTION

1. The Pan American Health Organization (PAHO) is the oldest public health agency in the world. It was founded by countries of the Americas in 1902 for the purpose of collaboratively addressing devastating epidemics of cholera, plague, typhus, influenza and other deadly diseases, as well as the growing spread of communicable diseases. In 1946, PAHO entered into an arrangement with the World Health Organization (WHO), pursuant to which it agreed to serve as its Regional Office for the Western Hemisphere, while maintaining its separate and independent identity as PAHO. As established by agreement between the Organization of American States (OAS) and PAHO in 1950, the Organization serves as the specialized health agency of the OAS, whose other specialized agencies include the Inter-American Development Bank and the Inter-American Institute for Cooperation on Agriculture. During its more than 110 year history, PAHO has worked with the singular intention of improving the health of the peoples of the Americas by providing technical cooperation and mobilizing partnerships to improve health and quality of life.

2. While the original focus of PAHO's work was in the area of communicable diseases, due to advances made in the treatment and control of endemic diseases, a changing demographic in the region and the effects of globalization, the Organization began to focus not only communicable diseases but also on noncommunicable diseases (NCDs), such as cancer, diabetes, and cardiovascular and respiratory diseases. While these NCDs can be caused by a number of risk factors, in many cases they share a common risk factor – tobacco.

3. Tobacco products have unique characteristics that make them different from any other commodity or consumer product; they are highly engineered by the tobacco industry to create and sustain addiction.[1] Also, they are the only legal product that kills one third to one half of its consumers when used as intended by manufacturers.[2]

4. Globally, tobacco consumption kills approximately 5.1 million people per year[3] (12% of all deaths among adults aged 30 years and over)[4]; half of those deaths will occur in middle age.[5] Exposure to secondhand smoke kills an additional 603,000 people each year.[6] In total, tobacco is responsible each year for more deaths than tuberculosis, human immunodeficiency virus/acquired immunodeficiency

[1] World Health Organization, WHO Framework Convention on Tobacco Control (2003).

[2] Peto R; Lopez AD, Boreham J; Thun M; *Heath C, Mortality from tobacco in developed countries: indirect estimation from national vital statistics*, Lancet (1992).

[3] *WHO global report: mortality attributable to tobacco* (2012). Available at: http://www.who.int/tobacco/publications/surveillance/rep_mortality_attributable/en/. *See also*, World Health Organization, *WHO Global Health Risks: Mortality and burden of disease attributable to selected major risks* (2009). Available at: http://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf.

[4] *WHO global report: mortality attributable to tobacco* (2012).

[5] Doll R, Peto R, Wheatley K, Gray R, Sutherland I. *Mortality in relation to smoking: 40 years' observations on male British doctors*, BMJ (1994); 309:901. Available at: http://www.bmj.com/content/309/6959/901.

[6] *WHO global report: mortality attributable to tobacco* (2012). *See also*, World Health Organization, *WHO Global estimate of the burden of disease from second-hand smoke* (2011). Available at: http://www.who.int/tobacco/publications/second_hand/global_estimate_burden_disease/en/.

syndrome (HIV/AIDS), and malaria combined.[7] If no action is taken, by 2030 total annual tobacco-related deaths are projected to increase to more than 8 million.[8]

5. In the Americas, there are 145 million smokers representing 12% of the more than 1 billion smokers worldwide. In the Americas, tobacco use is responsible for 16% of all deaths of adults 30 years of age and over.[9] Together with second-hand smoke exposure, tobacco is responsible for approximately 1,000,000 deaths annually in the region.[10]

6. PAHO began working very closely with its Member States in the early 1960s to address the rapidly growing concern regarding the detrimental health effects of smoking.[11] Since that time, the Organization has provided its Member States with effective strategies and tools to reduce the burden of disease, death and economic consequences caused by tobacco use and exposure to second-hand smoke. In addition, PAHO has urged the sharing of information between Member States regarding tobacco industry strategies and tactics as a means of building and maintaining a strong and informed tobacco control stance in the region.

7. In light of growing rates of tobacco consumption globally and the grim statistics regarding the effects of tobacco use and second-hand smoke exposure, on 21 May 2003, the Fifty Sixth World Health Assembly adopted the World Health Organization Framework Convention on Tobacco Control ("WHO FCTC" or "Convention"). The WHO FCTC, which entered into force on 27 February 2005 and currently has 180 Parties, is a legally-binding treaty that commits Parties to develop and implement a series of evidence-based tobacco control measures, at country level, to stop the tobacco epidemic. It also provides detailed guidelines, policy options and recommendations intended to help Parties implement the WHO FCTC mandates. In short, it provides a means for a collective global response to the growing tobacco epidemic facing the world population.

8. Uruguay was an early signatory to the WHO FCTC, signing the treaty on 19 June 2003 and ratifying it on 9 September 2004. It was one of the first 40 countries to ratify the Convention, which then entered into force.[12]

9. Effective tobacco control measures, including implementation of those mandated under the WHO FCTC, have led to a decline in tobacco consumption in developed countries. In order to maintain their profits, the tobacco industry has consequently turned its attention to the developing world, heavily focusing on low income populations, women and especially young people with the aim of recruiting

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[7] *WHO global report: mortality attributable to tobacco*. (2012).

[8] World Health Organization, *WHO Tobacco Fact Sheet No. 339*. Updated May 2014. Available at: http://www.who.int/mediacentre/factsheets/fs339/en/.

[9] Pan American Health Organization/World Health Organization, *Tobacco Control Report for the Region of the Americas* , at 1 (2013). Available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=24768&Itemid.

[10] *Id.*

[11] PAHO has 35 Member States in North, Central and South America and the Caribbean, four Associate Members (Puerto Rico, Aruba, Curaçao and Saint Maarten), three Participating States (France, the Netherlands, and the United Kingdom), and two Observer States (Portugal and Spain).

[12] World Health Organization, *WHO Framework Convention on Tobacco Control* (2003), Status of Signatories and Parties to the Convention. Available at: https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4&chapter=9&lang=en. *See also*, Parties to the WHO Framework Convention on Tobacco Control. Available at: http://who.int/fctc/signatories_parties/en/.

"replacement smokers" as long-time smokers either die or quit.[13] At present, most tobacco-related deaths occur in low- and middle-income countries and are expected to increase over the next several decades.[14]

10. As the tobacco epidemic in the Americas continues to grow, countries such as Uruguay are taking a strong stand to protect the health and wellbeing of their citizens, particularly vulnerable populations such as young people. Faced with this opposition, the tobacco industry has implemented increasingly aggressive strategies and deceptive practices to derail, undermine and circumvent governmental tobacco control regulations and other initiatives.[15]

11. Uruguay recently introduced labelling and packaging rules that require health warnings that cover 80% of the front and back of cigarette packs (the "80% Rule") and a prohibition on the marketing of multiple presentations of the same brand of cigarettes (the "Single Presentation Rule" or "SPR").

12. PAHO fully supports Uruguay and its reasonable, good faith efforts to develop a tobacco control strategy and rules – such as the 80% Rule and the SPR – that protect the right of its citizens to health and also respond to the ever-changing strategies employed by the tobacco industry to continue selling a product that is harmful to public health. Article 44 of Uruguay's Constitution specifically authorizes the government of Uruguay to enact legislation on all questions of public health, with the purpose of attaining the physical, moral and social improvement of Uruguay's citizens.[16] Moreover, Uruguay's actions in implementing the 80% Rule and the SPR are consistent with its obligations as a Party to the WHO FCTC, various international human rights treaties, and the regional strategy developed by PAHO and its Member States to combat tobacco use and exposure.[17]

B. THE TOBACCO EPIDEMIC IN THE REGION OF THE AMERICAS

13. In the 1960s, PAHO and its Member States publicly confirmed tobacco use as a serious health threat to the region and began focusing on coordinated prevention measures as a first line of defense against tobacco-related diseases.

14. In September/October 1969, PAHO Member States officially declared that smoking cigarettes is hazardous to one's health and is a significant factor in premature death from bronco pulmonary cancer, coronary illness, chronic bronchitis and chronic respiratory insufficiency. Member States instructed PAHO to prepare a report on measures taken to control cigarette advertising by restricting promotional

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[13] Tobacco Control Legal Consortium, *The Verdict is in. Findings from Unites States v. Phillip Morris. Marketing to Youth* (2006). Available at: *http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-youth.pdf*.

[14] World Health Organization, *WHO Report on the Global Tobacco Epidemic*, at 8 (2009). Available at: http://whqlibdoc.who.int/publications/2009/9789241563918_eng_full.pdf.

[15] Alderete Mariela, *Health is not negotiable* 2nd Edition, Civil Society against the Tobacco Industry's Strategies in Latin America. Case Studies (2014). Available at: https://www.stopcorporateabuse.org/sites/default/files/resources/2014_health_is_not_negotiable_-_colombia_2nd_ed_0.pdf. *See also*, World Health Organization, *Tobacco Industry Interference with Tobacco Control* (2008). Available at: http://whqlibdoc.who.int/publications/2008/9789241597340_eng.pdf?ua=1.

[16] Constitution of the Oriental Republic of Uruguay, 27 November 1966. Available at: http://www.refworld.org/docid/3ae6b5600.html.

[17] *See*, Pan American Health Organization, 19th PAHO Directing Council, Resolution DC19/R34 (Sept./Oct. 1969); 18th Pan American Sanitary Conference, Resolution PSC 18/R35 (Sept.Oct.1970); PAHO 33rd Directing Council, Resolution CD33.R22 (1988); PAHO 43rd Directing Council, Document CD43/13; also Resolution CD43.R12 (2001).

material or through the inclusion of health warnings; of other possible means of warning the public about the hazards of cigarette smoking; and of measures that could be taken to control cigarette smoking in work places or public meetings.[18]

15. In September/October 1970, all countries in the Americas region mandated intensified and coordinated efforts against tobacco consumption; recognized the Organization's initiative in establishing a survey regarding the characteristics of tobacco smoking in eight cities in Latin America; tasked PAHO's Director with initiating such surveys in other Latin American countries where there was a desire to control cigarette consumption; and advised PAHO's Director to establish an office devoted to compiling and disseminating information concerning smoking and health.[19]

16. In 1988, PAHO Member States re-affirmed the need for strong tobacco control efforts in the region. Member States were advised to implement public health measures at the regional and national levels to prevent and control the use of tobacco as well as to protect the health of nonsmokers.[20] They were also advised to restrict smoking in public places; to control direct and indirect advertisement of tobacco products; to establish educational programs at all educational levels, and to increase public awareness of the dangers of smoking. PAHO was also asked by its Member States to elaborate a Plan of Action for the prevention and control of tobacco use.[21] The Action Plan was subsequently presented and adopted by PAHO Member States in September 1989.[22]

17. Despite the efforts of PAHO and its Member States, the effectiveness of tobacco control legislation in the region continued to be limited. By the 1990s, tobacco use was a leading cause of premature death in the Americas. Tobacco-attributable deaths stood at 670,000 deaths per year.[23] At that time, tobacco use was widely accepted, the public was poorly informed about its harmful effects, and compliance with existing tobacco control measures was poor.

18. Moreover, the advertising and promotion of tobacco by transnational companies was increasing in order to capture new markets. The tobacco industry's push to expand its market was successful in countries where policies and programs for tobacco control were not adequate to stem the industry's aggressive international marketing.[24]

19. By 2002, the highest tobacco consumption rates were found in the southernmost areas of South America, especially Argentina, Chile, and Uruguay with prevalence rates ranging from 38% to 47% for

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[18] Pan American Health Organization, 19th Directing Council, Resolution DC19/R34 (Sept./Oct. 1969). Available at: http://iris.paho.org/xmlui/bitstream/handle/123456789/2604/CD19.R34en.pdf?sequence=1.

[19] Pan American Health Organization, 18th Pan American Sanitary Conference, Resolution PSC 18.R35 (Sept./Oct. 1970). Available at: http://iris.paho.org/xmlui/handle/123456789/5529.

[20] Pan American Health Organization, 33rd Directing Council, Resolution CD33.R22 (1988). Available at: http://iris.paho.org/xmlui/bitstream/handle/123456789/1492/CD33.R22en.pdf?sequence=1.

[21] *Id*.

[22] Pan American Health Organization, 34th Directing Council, Resolution CD34R12 (1989). Available at: http://iris.paho.org/xmlui/handle/123456789/1529.

[23] PAHO 43rd Directing Council, Document CD43/13; also Resolution CD43.R12 (2001). Available at: http://iris.paho.org/xmlui/bitstream/handle/123456789/1442/cd43.r12-e.pdf?sequence=1.

[24] PAHO 25th Pan American Sanitary Conference. Document CSP 25/11 (1998). Available at: http://www1.paho.org/english/gov/csp/csp25_11.pdf?ua=1.

men and from 26% to 35% for women.[25] In 2003, the prevalence rate in Uruguay was 33.3% (38.8% in men and 24.8% in women).[26] As in the rest of the region, smoking was a socially accepted behavior in Uruguay and public awareness regarding the risks of tobacco use was low.[27]

20. At that time, an average of 14 Uruguayans per day died of tobacco-related diseases,[28] despite tobacco control legislation enacted in 1982.[29] This legislation contained restrictions on tobacco product advertisements and mandated the use of text-only health warnings on tobacco packages and in advertising (*i.e.*, a statement that smoking is detrimental to health). The legislation also banned sales of tobacco to minors and prohibited the sale of individual cigarettes. Regulations restricted smoking in some modes of transportation and banned certain promotional activities.[30] In 1996, Uruguay enacted a decree banning smoking in public places but allowing smoking in designated areas.[31]

21. In 2002, a multicenter study sponsored by PAHO measured airborne nicotine levels in public spaces and concluded that Argentina and Uruguay shared the dubious distinction of having the highest levels of tobacco smoke pollution among the seven countries studied. Moreover, the study demonstrated the ineffectiveness of separating smokers from nonsmokers in a single environment.[32]

22. Currently, chronic NCDs, such as cardiovascular diseases, cancers, diabetes, and respiratory diseases, are responsible for 77% of all deaths in the Americas. Among these, tobacco is responsible for 15% of deaths from cardiovascular diseases, 26% of deaths from cancer, and 51% of deaths from respiratory diseases.[33]

23. In Uruguay, NCDs are estimated to account for 85% of total deaths.[34] Consumption of tobacco and exposure to tobacco smoke (common risk factors for the main NCDs noted above) are responsible for

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[25] Pan American Health Organization, *Health in the Americas*, Vol. 1 (2002). Available at: http://www2.paho.org/saludenlasamericas/dmdocuments/health-americas-2002-vol-1.pdf.

[26] World Health Organization, *WHO Report on the Global Tobacco Epidemic, 2008. The MPOWER package*. *See*, Table 4.2 Adult tobacco surveys in WHO Member States. Available at: http://www.who.int/tobacco/mpower/mpower_report_full_2008.pdf.

[27] Esteves, Dra. Elba et al, *Uruguay libre de humo de tabaco… y después? El equipo e salud y las políticas de control de tabaco*. Comisión Honoraria para la Salud Cardiovascular (2007). Available at: http://www.cardiosalud.org/files/documents/chscv_uruguay_libre_humo.pdf.

[28] *Id.*

[29] Oriental Republic of Uruguay, Ley No. 15.361 Cigarrillos, cigarros y tabacos. Se adoptan disposiciones sobre publicidad y comercialización. December 1982. Available at: http://www.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=15361&Anchor.

[30] Decree 407/981 from the Ministry of Transportation. Decree 142/998 from Ministry of Health.

[31] Decree 203/96 (28 May 1996).

[32] Blanco Marquizo, A., *Six years that changed tobacco control in Uruguay: lessons learned*. PAHO (2007). Available at: http://www2.paho.org/hq/dmdocuments/2010/Lessons-learned-ENG.pdf. *See also,* Ana Navas Acien, *Secondhand tobacco smoke in public places in Latin America, 2002-2003*. et al, JAMA (June 9, 2004), Vol. 291, No22 2741- 2745.

[33] World Health Organization, *WHO Global status report on Noncommunicable diseases 2010*. Available at: :http://whqlibdoc.who.int/publications/2011/9789240686458_eng.pdf .

[34] World Health Organization, *Non-communicable diseases country profiles 2014*. Available at: http://www.who.int/nmh/countries/ury_en.pdf?ua=1.

15% of all deaths for Uruguayans over 30 years of age, which is higher than the world average of 12%.[35]

24. The Americas ranks fourth among the six WHO regions in tobacco consumption.[36] In the Americas region, 22% of adults smoke. Within the Americas, the prevalence of tobacco smoking among adults varies widely between countries, from 41% in Chile to 7% in Barbados.[37] In Uruguay, according to the 2009 Global Adult Tobacco Survey (GATS), 25% of people 15 years of age and older currently smoke tobacco, a rate which was above the regional average prevalence of 22%.[38]

25. Data from the WHO Global Youth Tobacco Survey (GYTS) are also not encouraging. The prevalence of consumption of tobacco products in adolescents 13 to 15 years of age ranges from 35.1% in Santiago de Chile to 7.8% in the U.S. Virgin Islands. Moreover, 23.4% of this age group surveyed in the Americas reported they would probably initiate tobacco use within the next year.[39] In the case of Uruguay, the 2007 GYTS showed that 23.2% of adolescents aged 13 to 15 used tobacco products at the time.[40]

26. Rising consumption rates among women are a particularly disturbing feature of smoking in the Americas. This pattern is not seen to the same extent in other regions of the world.[41] This aspect is even more pronounced with respect to cigarette consumption among girls between the ages of 13 and 15 years (12.3% prevalence in boys, 11.3% prevalence in girls). Indeed, in some countries of South America, there is even a reversal of the traditional male/female ratio in this age range, with girls consuming more tobacco than boys.[42] Uruguay is a good example of this phenomenon, with 21.4% of boys and 24.5% of girls between the ages of 13 and 15 using tobacco products, according to the GYTS 2007.[43] The increasing feminization of consumption is driven by, among other things, the aggressive effort by the tobacco industry to promote their products, especially to women and young people.[44]

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[35] *WHO Global Report: Mortality Attributable to Tobacco 2012*.

[36] World Health Organization, *Gender, women and the tobacco epidemic 2010*. Available at: http://www.who.int/tobacco/publications/gender/women_tob_epidemic/en/.

[37] Pan American Health Organization/World Health Organization, *Tobacco Control Report for the Region of the Americas*, at 1 (2013) p 1.

[38] World Health Organization, *Global Adult Tobacco Survey (GATS) Fact Sheet, Uruguay 2009*. Available at: http://www.who.int/tobacco/surveillance/fact_sheet_of_gats_uruguay_2010.pdf.

[39] Pan American Health Organization, *Youth and tobacco in the Americas: Results from the Global Youth Tobacco Survey 2000-2010* (2012). Available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&Itemid=270&gid=24894&lang=en.

[40] Global Youth Tobacco Survey (GYTS), Uruguay, Fact Sheet, *(ages 13 – 15)*. Available at: http://www2.paho.org/hq/dmdocuments/2010/2007%20Uruguay%20GYTS%20Factsheet%20(Ages%2013-15).pdf.

[41] World Health Organization, *Gender, women and the tobacco epidemic 2010*.

[42] Pan American Health Organization, Youth and tobacco in the Americas: Results from the Global Youth Tobacco Survey 2000-2010, Washington DC 2012.

[43] Global Youth Tobacco Survey (GYTS), Uruguay, Fact Sheet, (ages 13 – 15).

[44] Pan American Health Organization, *Manual for Developing Tobacco Control Legislation in the Region of the Americas, 2013*. Available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=24890&Itemid.

27. As PAHO Member States pursued regulatory efforts to discourage tobacco use, tobacco industry strategies evolved to sidestep those efforts. For example, the introduction of new forms of tobacco products (*e.g.*, smokeless tobacco, light cigarettes) and deceptive practices in the sales, marketing and manufacturing of tobacco products were attempts by the tobacco industry to "contribute to tobacco use and addiction by fostering initiation among young people; making products easier and more acceptable to use; making and marketing products so as to seemingly address health concerns; and making and marketing products to perpetuate addiction through the use of alternative products when smoking is not allowed."[45] While tobacco products vary widely in form, content and emissions, virtually all types are primarily represented by products that are designed and manufactured with the sole purpose of delivering nicotine, the chemical responsible for the addictiveness of tobacco, thus ensuring continuing sales of this deadly product.

C. THE TOBACCO INDUSTRY'S STRATEGY OF DECEPTION AND OBSTRUCTION

- **The Tobacco Industry's Deceptive Practices in the Americas**

28. The global tobacco epidemic has been fueled by tobacco industry practices intended to deceive the public regarding the health hazards of tobacco use, to create new and more addictive products, and to avoid, delay or circumvent regulation. Because of the tobacco industry's long history of public deception, product manipulation, and targeted marketing to young people, there is a clear need for a strong global approach to tobacco control.

29. In 1998, previously confidential internal tobacco industry documents became public as a result of litigation in the United States of America brought by the Attorneys General of forty-six U.S. states, five U.S. territories, and the District of Columbia against the five largest tobacco companies in the United States, including Philip Morris. That litigation resulted in the Master Settlement Agreement (MSA), an accord between the parties concerning the advertising, marketing and promotion of tobacco products. In addition to requiring the tobacco industry to pay the settling states approximately $10 billion annually for the indefinite future, the MSA also set standards for, and imposed restrictions on, the sale and marketing of cigarettes by participating cigarette manufacturers.[46]

30. Those internal industry documents provided evidence of the tobacco industry's long history of deceptive practices in the sales, marketing and manufacturing of tobacco products and revealed the extensive research, manufacturing and marketing efforts undertaken by the tobacco industry to make their products more addictive, thus ensuring a constant stream of lifetime smokers and perpetual profits.

31. Not only was the recruitment of new smokers important for the tobacco industry, the internal documents also show that in the face of growing evidence of the risk associated with tobacco use there was a need to retain the current smokers. Industry documents discussed the need to "reassure" worried smokers in order to retain them in the market. In the industry's own words:

> *All work in this area should be directed towards providing consumer reassurance about cigarettes and the smoking habit. This can be provided in different ways, e.g. by claimed low deliveries, by the perception of low deliveries and by the perception of 'mildness.' Furthermore advertising for low delivery or traditional*

[45] US Department of Health and Human Services, *The Health Consequences of Smoking- 50 Years of Progress, A Report of the Surgeon General,* at 784 (2014). Available at: http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.

[46] Master Settlement Agreement (1998). Available at: http://publichealthlawcenter.org/sites/default/files/resources/master-settlement-agreement.pdf.

> *brands should be constructed in ways so as not to provoke anxiety about health, but to alleviate it, and to enable the smoker to feel reassured about the habit and confident in maintaining it over time.* [Emphasis in original] [47]

32. In November 2002, PAHO published "*Profits over People. Tobacco Industry Activities to Market Cigarettes and Undermine Public Health in Latin America and the Caribbean.*" The report was the culmination of the Organization's review of thousands of pages of documents pertaining to the activities of global industry leaders Philip Morris and British American Tobacco in Latin America. These documents, like others released as a result of litigation, revealed industry-wide efforts to thwart and subvert the intent of national tobacco control efforts that would restrict the companies' deceptive promotional and marketing strategies, as well as the sale and distribution of their products.

33. The summary of findings in PAHO's 2002 report reveal how the tobacco industry and its agents developed strategies and engaged in activities designed to influence political decisions in a manner favorable to the industry and against the interests of public health. One conclusion of the report:

> *The tobacco industry's general strategies for Latin America and the Caribbean are similar to those used in other regions of the world. While the two dominant players, British American Tobacco (BAT) and Philip Morris International (PMI), fight each other for market share, they also cooperate to pressure governments on tax, pricing and legislative issues while crying out publicly against state intervention in their corporate affairs. More importantly, BAT and PMI collaborate to mislead the media and, ultimately, the public, on the real risks of smoking and exposure to second-hand smoke, and about the strategies that effectively reduce tobacco use.*[48]

34. The report also describes the increased marketing, and subsequent growth in consumption, of the so-called "light" and "mild" brands in Latin America, and provides evidence that the tobacco industry intentionally sought to deceive health-conscious consumers into believing that "light" and "mild" brands are a healthier alternative to full flavored brands, just as it had done in North America more than a decade earlier. A Philip Morris meeting discussing the Latin America market describes forays into this market:

> *<u>Brazil- Golden Flanker Project</u>*
>
> *Factors: Down trading, switch to white tips (mildness perception), more female smokers. White tips- Galaxy, Luxor, Plaza, Hollywood losing to Free and Plaza, but Free also losing to Plaza and vice versa. To be economically feasible, product would be 12- 13mg, not truly LTN (low tar and nicotine). "Golden" will be endorsed by Galaxy, it's a mild product with flavor.*
>
> *<u>Project Suave</u>*
>
> *Category includes real and perceived LTN's with white tipping.*

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[47] British American Tobacco (1977). Bates no. 100427792/7800. Available at: http://legacy.library.ucsf.edu/action/document/page?tid=bvs56b00.

[48] Pan American Health Organization, P*rofits over People. Tobacco Industry Activities to Market Cigarettes and Undermine Public Health in Latin America and the Caribbean*, at 33 (2002). Available at: http://www1.paho.org/English/DD/PUB/profits_over_people.pdf.

Freshness is an important attribute (menthol is not desirable) Australia's "Forest" or ECC's "Vitality"
Pack- avoid green, use blue.
Product – hint of menthol. "Fresh Lights" - "the only cigarette with a touch of freshness."[49]

35. Deception as standard tobacco industry practice was a central finding of fact in the 2006 decision in *U.S. vs. Philip Morris, USA, Inc*.[50] In that case, the U.S. District Court for the District of Colombia found that Philip Morris had violated the Racketeer Influenced and Corrupt Organizations Act (RICO).

36. In its Final Opinion, the U.S. District Court found eleven of America's major tobacco companies guilty of nearly 150 counts of mail and wire fraud in a continuing "pattern of racketeering activity" with the "specific intent to defraud" under the RICO Act. It concluded, *inter alia*, that "the industry had marketed and sold their lethal products with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted."[51]

37. Moreover, the U.S. District Court found that there was sufficient evidence in the record to show that:

    - Defendants knew for more than fifty years that cigarette smoking caused disease, but repeatedly denied it. For decades, Defendants publicly distorted and minimized the dangers of smoking.[52]

    - Defendants concealed and suppressed research data and other evidence that nicotine is addictive. They also withheld information about their internal research on addiction from the American public, the government, and the public health community, including the United States Surgeon General. The Defendants did so in order to maintain profits by keeping people smoking and attracting new consumers, to avoid liability, and prevent regulation of the industry.[53]

    - Defendants falsely denied that they control the level of nicotine delivered to smokers to create and sustain addiction.[54]

    - Defendants falsely marketed and promoted low tar/"light" cigarettes as less harmful than "full flavor" cigarettes to keep people smoking and sustain corporate revenues.[55]

    - Beginning in the 1950s, different tobacco companies using different methods have intentionally marketed cigarettes to young people under the age of 21 in order to recruit

[49] *Id.*

[50] United States v. Philip Morris, USA, Inc., 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam) (hereinafter, "United States v. Philip Morris").

[51] *Id*., at 28.

[52] *Id*., at 219, 279.

[53] *Id.*, at 330-333, 447, 479-480.

[54] *Id*., at 514-517, 654.

[55] *Id*., at 741, 877, 879, 971.

"replacement smokers" who would ensure the future economic viability of the Tobacco Industry.[56]

- Defendants publicly denied, while internally acknowledging, that secondhand tobacco smoke is hazardous to nonsmokers.[57]

- At various times, Defendants attempted to, and did suppress and conceal scientific research and destroy documents relevant to their public and litigation positions.[58]

38. On appeal to the U.S. Court of Appeals for the D.C. Circuit, a three-judge panel, upheld the U.S. District Court's decision finding the tobacco companies liable.[59]

39. It is within the environment described above – one of tobacco industry manipulation, dishonesty and deceptive practice – that PAHO Member States must find ways to effectively control tobacco consumption and exposure.

- **The Tobacco Industry's Litigation Strategy in the Americas**

40. PAHO routinely advises public health authorities in the Americas in relation to the drafting of public health regulations, including with respect to tobacco control. In the course of providing such advice, and in its discussions with public health regulators more generally, PAHO has become aware that the threat of litigation is having a chilling effect on the promulgation of tobacco control measures, including those like Uruguay's, even though the measures are considered important for public health.

41. As global efforts to stem the tobacco epidemic and its heavy impact on individuals, families and society have increased, so has the tobacco industry's efforts to maintain its market share. However, as pronounced by the United Nations General Assembly in 2011, "[There is a] fundamental conflict of interest between the tobacco industry and public health."[60]

42. Litigation is a tool often used by the tobacco industry to hinder legitimate public health regulations. Litigation imposes a significant financial burden on small countries such as Uruguay and acts as an impediment to implementation of effective tobacco control regulations. This strategy is particularly successful against low- and middle-income countries that attempt to legitimately regulate tobacco use as a means of protecting the health and wellbeing of their citizens.

43. The tobacco industry, and those working to further its interests, has used litigation as a response to the advancement of tobacco control regulation in the region and as a means of delay. In most cases, the tobacco industry uses constitutional claims in their attempt to weaken effective tobacco control measures. This has happened in almost every Latin American country after the passing of a tobacco

[56] *Id.* at e.g., 561, 562, 564, 692, 852.

[57] *Id.*, at e.g., 708, 759, 795, 796, 798, 865, 869.

[58] *Id.*, at 869.

[59] *Id.*

[60] United Nations General Assembly, Political Declaration on the High-Level Meeting for the General Assembly on the Prevention and Control of Non-communicable diseases, 2011. Available at: http://www.un.org/ga/search/view_doc.asp?symbol=A/66/L.1.

control law or regulation.[61] The tobacco industry knows that such litigation is not only very costly and time consuming for the party that must defend its tobacco controls laws and policies, but that it has an equally desirable chilling effect on other jurisdictions contemplating new tobacco control measures.[62] Even when the tobacco industry loses on the merits in litigation (as it usually does), it benefits financially from the resulting delays in tobacco control regulation implementation and from the uncertainty generated by its legal tactics.

44. Despite the tobacco industry's litigation tactics, court decisions have favored the right of governments to implement public health policies, not only at a national level but also at the local level.[63] In the United States, after analyzing ordinance level litigation, it was found that "despite the tobacco industry's well-earned reputation as a ferocious litigator, the fact is that the industry (and its front groups and allies) has not fared well when using the courts to challenge local tobacco control ordinances."[64]

45. In the face of the tobacco industry's litigation strategy, PAHO and its Member States have continually encouraged countries in the region to "oppose attempts by the tobacco industry or its allies to interfere with, delay, hinder, or impede the implementation of public health measures designed to protect the population from the consequences of tobacco consumption and exposure to second-hand smoke; [and] to recognize the need to monitor, document, and, according to national legislation in force, publicize the activities of the tobacco industry in order to make their strategies transparent and reduce their effectiveness.[65]

D. WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL (WHO FCTC)

46. As a direct consequence of the global nature of the growing tobacco epidemic, the multinational characteristics of the major tobacco industry, and the aggressive tobacco industry strategies to deceive consumers and undermine tobacco control efforts, in May 1995 the Forty Eighth World Health Assembly – the highest level of governing authority for the World Health Organization – asked the WHO Director-General to develop a report on the feasibility of developing an international instrument such as guidelines, a declaration or an international convention on tobacco control.[66] This was the impetus for the WHO FCTC.

47. The reaction of the tobacco industry to the WHO FCTC negotiations was predictably negative.

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[61] O'Neill Institute for National and Global Health Law, *Tobacco Industry Strategy in Latin American Courts – A Litigation Guide*, at 16 (2012). Available at: https://www.law.georgetown.edu/oneillinstitute/documents/2012_OneillTobaccoLitGuide_ENG.PDF.

[62] J K Ibrahim and Stanton A Glantz, *Tobacco industry litigation strategies to oppose tobacco control media campaigns*, at 50. Tob Control 2006;15:50-58 doi:10.1136/tc.2005.014142.

[63] M L Nixon, L Mahmoud, S A Glantz, T*obacco industry litigation to deter local public health ordinances: the industry usually loses in court*, p. 71. Tobacco Control 2004;13:65–73.

[64] *Id*.

[65] Pan American Health Organization, 50th Directing Council. Resolution CD 50R6, *Strengthening the Capacity of Member States to Implement the Provisions and Guidelines of the WHO Framework Convention on Tobacco Control* (2010). Available at: http://www2.paho.org/hq/dmdocuments/2010/CD50.R6-e.pdf.

[66] World Health Organization, *History of the WHO Framework Convention on Tobacco Control* (2009). Available at: http://whqlibdoc.who.int/publications/2009/9789241563925_eng.pdf?ua=1&ua=1.

48. During the WHO FCTC negotiations, then-WHO Director-General Dr. Gro Harlem Brundtland, alerted by information contained in private industry documents released as a result of litigation, convened an external committee, the Committee of Experts on Tobacco Industry Documents, to investigate the possibility of tobacco industry direct interference in WHO's work on tobacco control.[67] In its final report, the Committee concluded, *inter alia*, that, ". . . tobacco companies have operated for many years with the deliberate purpose of subverting the efforts of the World Health Organization to control tobacco use. The attempted subversion has been elaborate, well-financed, sophisticated and usually invisible… The tobacco companies . . . viewed WHO . . . as one of their foremost enemies . . . (and) instigated global strategies to impede WHO's ability to carry out its mission."[68] These conclusions were supported by the aforementioned industry documents, including ones disclosed after the Master Settlement Agreement.

49. Despite tobacco industry efforts to undermine the WHO FCTC, on 21 May 2003, it was unanimously adopted by the Fifty Sixth World Health Assembly.[69]

50. The WHO FCTC – the first international treaty negotiated under the authority of WHO's Constitution – entered into force on 27 February 2005 and currently has 180 Parties, 30 of them in the Americas region.[70] The WHO FCTC has become one of the most rapidly and widely embraced treaties in United Nations' history and reaffirms the right of all people to the highest standard of health.[71]

51. The overarching objective of the WHO FCTC, as stated in Article 3, is to "protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke . . ."

52. In order to fulfill its goal of protecting present and future generations from the wide-ranging harms caused by tobacco, the WHO FCTC establishes comprehensive measures aimed at reducing the prevalence of tobacco consumption and exposure to tobacco smoke.

53. The measures intended to reduce the demand for tobacco are contained in Articles 6 through 14 of the WHO FCTC. Article 6 includes tax and price measures. Nonprice measures to reduce the demand for tobacco, include:

    - Protection from exposure to tobacco smoke (Article 8);
    - Regulation of tobacco product contents and emissions and disclosures of information on constituents and emissions (Articles 9 and 10);
    - Packaging and labeling of tobacco products (Article 11);
    - Education, communication, training, and public awareness (Article 12);
    - Tobacco advertising, promotion, and sponsorship (Article 13); and
    - Demand-reduction measures concerning tobacco dependence and cessation (Article 14).

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[67] *Id.*, at 8.

[68] *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization*. Report of the Committee of Experts on Tobacco Industry Documents. (July 2000). Available at: http://www.who.int/tobacco/en/who_inquiry.pdf; *See also*, *Id*.

[69] World Health Organization, 56th World Health Assembly, Resolution 56.1 (2003). Available at: http://www.who.int/tobacco/framework/final_text/en/index1.html.

[70] World Health Organization, *WHO Framework Convention on Tobacco Control.* Status of Signatories and Parties to the Convention.

[71] World Health Organization, *History of the WHO Framework Convention on Tobacco Control* (2009), at 5.

54. WHO FCTC measures intended to address access to tobacco include:

    - Prevention and elimination of illicit trade in tobacco products (Article 15);
    - Prevention of youth access to tobacco products (Article 16); and
    - Promotion of economically viable alternatives for tobacco workers, growers, and, as appropriate, sellers (Article 17), with due regard for protection of the environment and the health of persons involved in tobacco cultivation and manufacture (Article 18).

55. In developing and implementing these measures, the WHO FCTC requires Parties to protect public health policies regarding tobacco control from the commercial and other vested interests of the tobacco industry (Article 5.3); to make provisions for criminal and civil liability, including compensation where appropriate (Article 19); and to initiate and cooperate in research and surveillance programs and to exchange scientific, technical, and legal information (Articles 20–22).

56. None of the articles of the WHO FCTC, standing alone, can end the tobacco epidemic. This can only be achieved by implementation of the full package of measures included in the Convention. This does not mean that Parties must implement all measures at the same time; however, the final goal is the complete implementation of the Convention by all Parties.

57. Article 7 of the WHO FCTC requires the Governing Body of the Convention, known as the Conference of the Parties (COP), to propose guidelines for implementation of Articles 8 through 13 of the Convention. Developed through a wide, consultative, intergovernmental process, which includes the review of available scientific evidence and Party experience in implementing tobacco control measures, the Guidelines cover a wide range of provisions of the Convention. The Guidelines are adopted by the COP by consensus.

58. The Guidelines set forth principles, definitions, and key legislative elements that Parties agree are necessary to fulfill their obligations under the relevant WHO FCTC articles. In some cases they provide legislative elements that will enhance the effectiveness of the Convention's measures. This is supported by Article 2.1 of the WHO FCTC, which states that in order to better protect human health, Parties are encouraged to implement measures beyond those required by the Convention and its protocols. Parties should, therefore, enact the most effective and protective measures possible, consistent with their constitutional and other international legal obligations.

59. Finally, Party implementation of the WHO FCTC mandates is not static. Article 5.1 requires each Party to "... periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programs in accordance with this Convention and the protocols to which it is a party."[72] Emerging tobacco industry strategies and practices, new scientific data, and actual experience implementing specific control measures – among other factors – will influence how a Party to the WHO FCTC continues to shape its tobacco control program. Not only is this to be expected but it is required under the Convention.

[72] WHO Framework Convention on Tobacco Control, Art. 5.1.

E. THE WHO FCTC AND HUMAN RIGHTS OBLIGATIONS IN THE AMERICAS

60. It is also extremely relevant to note the strong connection between the WHO FCTC and human rights laws and obligations.[73] The Preamble of the WHO FCTC expressly links the tobacco control treaty to the three international human rights treaties listed below, to which both Uruguay and Switzerland are Parties:

- International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 12.[74]
    - Uruguay ratified the ICESCR on 1 April 1970.
    - Switzerland acceded to the ICESCR on 18 June 1992.
- Convention on the Rights of the Child (CRC).[75]
    - Uruguay ratified the CRC in 1990.
    - Switzerland ratified the CRC in 1997.
- Convention on the Elimination of All Forms of Discrimination against Women (CEDAW).[76]
    - Uruguay ratified the CEDAW in 1990.
    - Switzerland ratified the CEDAW in 1997.

61. The human rights protected by the WHO FCTC include the rights to life, to health, to work, and to live in a healthy environment, and the right of boys and girls to live and grow in such an environment, among others. These human rights are recognized at the international, regional, and constitutional levels; generate concrete legal obligations for the Parties to the human rights treaties; and give concrete content to general obligations to respect, protect, and fulfill the right to health with regard to the tobacco epidemic.[77]

62. In short, the human rights protected under the WHO FCTC and the human rights treaties ratified by States in the Americas expand the technical resources available to support the promotion and implementation of effective tobacco control measures, including those implemented by the government of Uruguay.

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[73] Cabrera, Oscar A. and Gostin, Lawrence O. Human rights and the Framework Convention on Tobacco Control: mutually reinforcing systems. International Journal of Law in Context, Vol. 7, pp 285-303. DOI : Published online: 20 September 2011. Available at: http://dx.doi.org/10.1017/S1744552311000139.

[74] International Covenant on Economic, Social and Cultural Rights, GA res. 2200A (XXI), 21 UN GAOR Supp. (No. 16) at 49, UN Doc. A/6316 (1966); 993 UNTS 3; 6 ILM 368 (1967).

[75] Convention on the Rights of the Child, GA res. 44/25, annex, 44 UN GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989); 1577 UNTS 3; 28 ILM 1456 (1989).

[76] Convention on the Elimination of All Forms of Discrimination against Women, GA res. 34/180, 34 UN GAOR Supp. (No. 46) at 193, UN Doc. A/34/46; 1249 UNTS 13; 19 ILM 33 (1980).

[77] Cabrera, O. and Madrazo A., *Human rights as a tool for tobacco-control in Latin America* (2010). Salud Pública de México, Vol. 52, supl. 2.

F. PACKAGING AND LABELING OF TOBACCO PRODUCTS UNDER THE WHO FCTC

63. Article 11 of the WHO FCTC mandates that Parties adopt and implement, in accordance with their national laws, effective measures to ensure that outside packaging and labeling used in the retail sale of tobacco products meet the following criteria:

> (*a) . . . [they] do not promote these products by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar," "light," "ultra-light" or "mild," and*
>
> *(b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use . . . These warnings and messages:*
>
> *(i) should be approved by the competent national authority;*
> *(ii) shall be rotating;*
> *(iii) shall be large, clear, visible and legible;*
> *(iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas; [and]*
> *(v) may be in the form of or include pictograms.* [78]
>
> [Emphasis added]

64. The Guidelines for implementation of Article 11 are intended to assist Parties in meeting their obligations under Article 11 of the treaty and to propose measures that Parties can use "to increase the effectiveness of their packaging and labeling measures."[79] One of the Guideline principles states, "Parties should consider the evidence and the expertise of others when determining new packaging and labeling measures and aim to implement the most effective measures they can achieve."[80]

65. A recent review of health warnings on tobacco products shows extensive evidence reaffirming that health warnings are effective. Specifically, health warnings have been found to:

- Increase health knowledge about the harms of tobacco;
- Prevent relapse in former smokers;
- Deter youth and adults from initiating use and experimentation;
- Deter smokers from lighting a cigarette;
- Increase smokers' intentions and attempts to quit;
- Reduce the appeal of the cigarette pack; and
- Promote the use of smoking cessation resources. [81]

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[78] WHO Framework Convention on Tobacco Control, Art. 11.

[79] WHO FCTC Guidelines for the Implementation of Art. 11, Guidelines on packaging and labelling of tobacco products, at para. 1. Available at: http://www.who.int/fctc/guidelines/adopted/article_11/en/.

[80] *Id*., at para. 4.

[81] Institute for Global Tobacco Control, State *of the evidence review. Health Warning Labels on Tobacco Products*. Baltimore MD: Johns Hopkins Bloomberg School of Public Health (October 2013).

66. The Guidelines also provide recommendations for the size of design elements. The Guidelines state, "Given the evidence that the effectiveness of health warnings and messages increases with their size, Parties should consider using health warnings and messages that cover more than 50% of the principal display areas and aim to cover as much of the principal display areas as possible."[82] They also emphasize that evidence shows "health warnings and messages that contain both picture and text are far more effective than those that are text-only." [83]

67. In relation to the content of the warnings, the Guidelines for Article 11 state, "evidence suggests that health warnings and messages are likely to be more effective if they elicit unfavorable emotional associations with tobacco use . . ."[84]

68. In order to develop effective packaging and labeling restrictions, Article 11 Guidelines recommend preventing the use of misleading or deceptive packaging and labeling, and implementing a ban on misleading descriptors, (such as "mild," "light" and "low tar") including "any term, descriptor, trademark or figurative or other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than others" and banning the "display of figures for emissions yields, including when used as part of a brand name or a trademark . . . The marketing of cigarettes with stated tar and nicotine yields has resulted in the mistaken belief that those cigarettes are less harmful."[85]

69. Recent research conducted in Canada, the United Kingdom, and Australia suggests, however, that prohibiting the terms "light," "mild," and "low tar," standing alone, may be insufficient to significantly reduce false beliefs about the health risks of different cigarette brands.[86] One potential explanation for these findings was the wide range of other designs and descriptors adopted by the tobacco industry, in the face of the ban on descriptors such as "light" and "mild," to subtly convey misleading information regarding the relative health risks caused by their products across brand families. This includes using colors across the different brand variants in a brand family, both on the packaging and in the brand name, such as "gold" and "silver." Research indicates that consumers perceive the color descriptors in the same way as the "light" and "mild" descriptors they replace. For example, more than three quarters of adults surveyed in the United States indicated that a brand labeled as "silver" would have lower levels of tar and fewer health risks than a "full flavor" brand.[87]

70. Finally, with respect to plain packaging, the Article 11 Guidelines state, "Parties should consider adopting measures to restrict or prohibit the use of logos, colors, brand images or promotional information on packaging other than brand names and product names displayed in a standard color and font style (plain packaging). The basis of the plain packaging requirements stem from efforts to "increase the noticeability and effectiveness of health warnings and messages, preventing the package

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[82] WHO FCTC Guidelines for the Implementation of Art. 11, Guidelines on packaging and labelling of tobacco products, at para. 12.

[83] *Id.*, at para. 14. *See also*, Bansal-Travers M, Hammond D, Smith P, Cummings M., T*he impact of Cigarette Pack Design, Descriptors, and Warning Labels on Risk Perception in the U.S.*, Am J Prev Med.2011 June; 40(6):674-682.

[84] WHO FCTC Guidelines for the Implementation of Art. 11, Guidelines on packaging and labelling of tobacco products, at para. 26.

[85] *Id.*, at para. 43.

[86] Hammond D., *Tobacco labeling toolkit: A guide to implementing FCTC Article 11*. Available at: www.tobaccolabels.org.

[87] Bansal-Travers M, Hammond D, Smith P, Cummings KM. The impact of cigarette pack design, descriptors, and warning labels on risk perception in the U.S. Am. J. Prev. Med. 2011 Jun 40(6):674-82. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21565661.

from detracting attention from them, and addressing industry package design techniques that may suggest that some products are less harmful than others."[88]

71. Article 13 of the WHO FCTC specifically recognizes that a comprehensive ban on advertising, promotion and sponsorship of tobacco products will reduce consumption. Consequently Parties are required to institute a comprehensive ban on all tobacco advertising, promotion and sponsorship within five years of the treaty's entry into force for that Party. "Advertising and promotion" are defined at Article 1(c) of the WHO FCTC as, "any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly."[89] "Tobacco Sponsorship" is defined at Article 1(g) as "any form of contribution to any event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly."

72. Where a comprehensive ban is not possible under a Party's constitution or constitutional principles, the Party is required to put forward as comprehensive a ban as possible. "As a minimum," parties are required to "prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions."[90]

73. The Article 13 Guidelines also recognize that packaging is an important element of advertising and promotion and that tobacco pack or product features are used in various ways to attract consumers. This effect can be eliminated by requiring plain packaging. Nevertheless, if plain packaging is not yet mandated by a Party, the restriction should cover as many as possible of the design features of the pack.[91]

74. The above provisions reflect global efforts, through the regulatory framework established under the WHO FCTC, to offset the deceptive practices that have been a trademark of the tobacco industry for decades. Specifically, Article 11 provides that Parties must require clear health warnings regarding the dangers of smoking and that those warning should be 50% or more of the principle display areas of the package, and in no case less than 30%. Correspondingly, Article 13 requires, at a minimum, that Parties ban tobacco advertising, promotion and sponsorship that may promote a tobacco product by "any means" that may create an erroneous impression that, for example, one tobacco product is less harmful to health than another. Under the Guidelines for implementation of Article 13 of the Convention, tobacco packaging and design are considered a form of tobacco advertising.[92]

75. Uruguay's 80% rule and SPR exemplify the regulatory provisions called for under Articles 11 and 13 of the WHO FCTC, as well as their relevant Guidelines.

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[88] WHO FCTC Guidelines for the Implementation of Art. 11, Guidelines on packaging and labelling of tobacco products, at para. 46.

[89] WHO Framework Convention on Tobacco Control, Art. 1(c) and (g). *See also*, Guidelines for implementation of Article 13 of the WHO Framework Convention on Tobacco Control (Tobacco advertising, promotion and sponsorship), at para. 7.

[90] WHO Framework Convention on Tobacco Control, Art 13(4)(a). *See also*, Guidelines for implementation of Article 13 of the WHO Framework Convention on Tobacco Control (Tobacco advertising, promotion and sponsorship), at e.g., paras. 1,35. Available at: http://www.who.int/fctc/guidelines/article_13.pdf?ua=1.

[91] Guidelines for implementation of Article 13 of the WHO Framework Convention on Tobacco Control (Tobacco advertising, promotion and sponsorship), at paras. 16 and 17.

[92] *Id.*, at Appendix.

G. TOBACCO CONTROL IN URUGUAY

76. Consistent with PAHO's regional tobacco control policies, and with the health of its citizens so obviously and seriously threatened by tobacco use, Uruguay became a Party to the WHO FCTC and committed to its full implementation by opting for the best practices described in the Convention and its Guidelines and applying them with an incremental approach.

77. The first measures applied by Uruguay after the WHO FCTC ratification were in the area of packaging and labeling, where Uruguay has shown a consistent approach by incorporating different scientifically-sound measures into legislation. For example, in 2003, Law 17.714 changed the text of the previous health warning to state that smoking may generate cancer, and lung and cardiovascular diseases. The warning also stated that smoking during pregnancy harms your baby.[93] However, the small size of the font and color of the warning did not change. In 2005 the government increased the size of the health warnings to at least 50% of principal surfaces[94] and added pictograms.[95] The use of misleading descriptors like "mild," "light," and "ultralight" were also banned to avoid a common misperception by Uruguayans that these products posed less of a risk to their health than other tobacco products.[96]

78. Out of Uruguay's participation in a series of "Smoke-free America" workshops held by PAHO, the "Smoke-free Uruguay project" was created. It culminated with the passage of Decree 268/005, which made Uruguay, in March 2006, the first country in the region to implement a total ban on smoking in enclosed public places, enclosed workplaces and on public transportation.[97]

79. In March 2008, Uruguay enacted Law 18256. Article 2 of the law mirrors the purpose of the WHO FCTC, which is to protect the population from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke.[98] Among other tobacco control measures, the law included a comprehensive ban on tobacco advertisement, promotion and sponsorship. It also forbade the use of terms, descriptive elements, manufacturers' or business brand names, figurative symbols or those of any other kind that have the direct or indirect effect of creating a false impression that a particular tobacco product is less harmful than another.

80. Finally, Law 18256 required clear, visible health warning and images or pictograms that describe the negative effects of tobacco consumption on at least 50% of the principle surfaces of tobacco product packaging. Enactment of Law 18256 was another important step in Uruguay's incremental approach to compliance with the WHO FCTC.

81. Consistent with this same approach to tobacco control and in keeping with Article 11(1)(b)(iv) of the WHO FCTC and relevant Guidelines -- which require that health warnings should be "50% or more of

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[93] Uruguayan Law 17,714 (2003).

[94] Ministry of Public Health Decree No.36 (2005). Available at: http://archivo.presidencia.gub.uy/decretos/2005012602.htm.

[95] Ministry of Public Health Ordinance No.171 (2005). Available at http://archivo.presidencia.gub.uy/_Web/noticias/2005/05/2005053107.htm.

[96] *Id*.

[97] Uruguay, Decreto No. 268/005 (2005). Available at: http://archivo.presidencia.gub.uy/_Web/decretos/2005/09/ASUNTO%20142_23%2008%202005_00001.PDF.

[98] Poder Legislativo. Ley 18.236 Medidas relacionadas con la reducción de la demanda de tabaco. March 2008. Available at: http://archivo.presidencia.gub.uy/_web/leyes/2008/03/S405_19%2010%202007_00001.PDF.

the principal display areas" of tobacco product packing -- in June 2009, Uruguay increased the size of the health warnings on tobacco products to 80% of principal surfaces, with new images being added at regular intervals.[99]

82. With the ban on misleading descriptors in place in Uruguay, cigarette manufacturers continued to find ways to misrepresent the health risks of their products. Some tobacco companies launched new variations of their brands, using design elements across brand families, like colors or numbers instead of words, to convey the false message that certain variants of their brands were less harmful than others. Even without such descriptors, many brands had been on the market for so long that consumers simply recognized the color scheme and logos on the cigarette pack and continued to associate those colors and logos with the earlier misleading descriptors.

83. As noted earlier, prohibiting the terms "light," "mild," and "low tar," standing alone, can be insufficient to significantly reduce false beliefs about the health risks of different cigarette brands.[100] Even after the removal of the terms "light" and "mild" from tobacco packages, a Canadian study found that 33% of smokers still reported that they used light brand variants.[101] Similar findings were reported in a U.S. study.[102]

84. Faced with this persistent threat to the health of its citizens, in 2009 Uruguay's Ministry of Health banned brand variations and required that only one variation of each brand could be sold in the country.[103]

85. In adopting the SPR, Uruguay was responding to precisely the same problem that caused Australia, and increasingly other countries, to adopt a plain packaging requirement; namely, that merely banning descriptors did not put an end to the false tobacco industry message, and resulting consumer belief, that some cigarettes are less harmful than others. Ecuador was actively considering following Uruguay's lead in adopting larger health warnings and an SPR but was dissuaded from doing so because of the pending litigation against Uruguay by the tobacco industry.

86. The effectiveness of Uruguay's regulatory initiatives can be seen in the positive impacts they have had in reducing tobacco consumption in that country. Between 2006 and 2012, approximately 1,400 adult smokers in Uruguay were interviewed as part of a face-to-face cohort survey to evaluate the effectiveness of Uruguay's tobacco control policies.[104] The survey was conducted as part of a

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[99] Ministerio de Salud Pública de Uruguay. Decreto 287/009. Available at: http://archivo.presidencia.gub.uy/_web/decretos/2009/06/CM751%20.pdf.

[100] Hammond D., *Tobacco labeling toolkit: A guide to implementing FCTC Article 11*.

[101] Cohen JE and Yang J, Donaldson E, *Impact of the removal of light and mild descriptors from cigarette packages in Ontario, Canada: Switching to "light replacement" brand variants*. Preventive Medicine. Vol 69 (Dec 2014) pg. 120-125. Available at: http://www.sciencedirect.com/science/article/pii/S0091743514003363#.

[102] Connolly G, Alpert H, *Has the tobacco industry evaded the FDA's ban on "light" cigarette descriptors*? Tob Control doi:10.1136/tobaccocontrol-2012-050746. Available at: http://tobaccocontrol.bmj.com/content/early/2013/03/01/tobaccocontrol-2012-050746.full#ref-19.

[103] Ministerio de Salud Pública Ordenanza Ministerial No. 514 (2009). Available at: http://www.tobaccocontrollaws.org/files/live/Uruguay/Uruguay%20-%20Ordinance%20No.%20514%20-%20national.pdf.

[104] The International Tobacco Control Policy Evaluation Project (August, 2014). ITC Uruguay National Report. Findings from the Wave 1 to 4 Surveys (2006-2012). University of Waterloo, Waterloo, Ontario, Canada; Centro de Investigación para la Epidemia del Tabaquismo and Universidad de la República, Uruguay. Available at: http://www.itcproject.org/files/ITC_Uruguay_Report-English-Sept24v24.pdf.

longitudinal cohort study of more than 20 countries, including Uruguay, carried out by the International Tobacco Control Policy Evaluation Project (ITC Project), the first international research program for the systematic evaluation of key policies of the WHO FCTC at population level.[105] The ITC Project survey of Uruguay provided evidence that Uruguay's policies regarding packaging and labeling were having a positive impact on public health and the environment. The findings also indicated that Uruguay must continue implementing strong measures to curb the use of deceptive tobacco product packaging and to make tobacco products less affordable.[106]

87. Specifically, the ITC Project found that Uruguay's 2009 implementation of pictorial warnings on 80% of the principal surfaces of cigarette packages had resulted in improvements in warning label effectiveness, which has been sustained by the introduction of new warning images in 2012. The percentage of smokers who reported that warning labels were a reason to think about quitting increased from 25% in 2008-2009 (when warnings were symbolic and covered 50% of the principal surfaces) to 31% in 2010-11 and 30% in 2012 (when the images were more graphic and covered 80% of the principal surfaces of the cigarette pack). In addition, gaps in smokers' awareness of stroke and impotence as smoking-related effects were reduced after the introduction of pictograms addressing these detrimental health impacts.[107]

88. The ITC Project also provides evidence of the positive impact of Uruguay's Single Presentation Rule. After Uruguay's implementation of the SPR, the percentage of smokers who believe – incorrectly – that light cigarettes are less harmful than regular cigarettes decreased from 29% to 15%.[108]

89. Other research likewise shows that Uruguay's tobacco control regulations have been effective. Specifically, an assessment of the impact of national tobacco control policies on three dimensions of tobacco use in Uruguay (per person consumption, adolescent prevalence, and adult prevalence) demonstrates consistent decreases in smoking in Uruguay since the country initiated a comprehensive control program in 2005.[109]

90. Studies also showed a 22% decrease in hospital admissions, between 2004 and 2008 in Uruguay, of individuals suffering heart attacks.[110] As indicated earlier, tobacco consumption is a risk factor for cardiovascular disease. Two years later, the decrease was found to have been sustained.[111] A separate study found that, as a result of Uruguay's tobacco control measures, the proportion of pregnant women

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[105] International Tobacco Control Policy Evaluation Project website. *See*, http://www.itcproject.org/.

[106] *Op. Cit.*

[107] *Id.*

[108] *Id.*

[109] Abascal W, Esteves E, Goja B, Gonzále Mora F, Lorenzo A, Sica A, Triunfo P, Harris JE. *Tobacco control campaign in Uruguay: a population based trend analysis*. Lancet Vol. 380 Nov 3, 2012. Available at: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60826-5/abstract.

[110] Sebrié E, Sandoya E, Hyland A, Glantz SA, Cummings KM. *Hospital admissions for acute myocardial infarction before and after implementation of a comprehensive smoke-free policy in Uruguay (2012)*. Tob Control doi:10.1136/tobaccocontrol-2011-050134. Available at: http://bmj-tobacco.highwire.org/content/early/2012/02/15/tobaccocontrol-2011-050134.abstract?related-urls=yes&legid=tobaccocontrol;tobaccocontrol-2011-050134v1&cited-by=yes&legid=tobaccocontrol;tobaccocontrol-2011-050134v1.

[111] Sebrié E, Sandoya E, Bianco E, Hyland A, Cummings KM, Glantz SA. *Hospital admissions for acute myocardial infarction before and after implementation of a comprehensive smoke-free policy in Uruguay: experience through 2010*. Tob Control doi:10.1136/tobaccocontrol-2012-050954. Available at: http://tobaccocontrol.bmj.com/content/early/2013/05/23/tobaccocontrol-2012-050954.abstract.

who had quit smoking in their third trimester increased markedly from 15% to 42% between 2007 and 2012.[112] Finally, while the 2007 GYTS showed that 23.2% of adolescents used tobacco products, preliminary data from the 2014 GYTS in Uruguay seems to indicate a significant decrease from the 2007 figure. Official data from the 2014 GYTS is expected to be published very shortly.

91. Each of the major non-price tobacco control measures – including programs to treat nicotine dependence in health centers, banning of advertising nationwide, rotating health warnings with pictograms, restriction of brands to a single presentation, and an increase in the size of pictograms to 80% of the front and back of tobacco packs – was separately associated with a significant increase in the rate of quitting.[113]

92. As a result of its leadership in the area of tobacco control and regulation, Uruguay is globally recognized as an expert and a model for other countries working towards effective national tobacco control programs.[114] As an example, on 21 May 2014, Uruguay agreed, through a Memorandum of Understanding with the WHO FCTC Secretariat, to have Uruguay's International Cooperation Centre on Tobacco Control (ICCTC) – a centre within Uruguay's Ministry of Public Health – function as a knowledge hub to promote the sharing of information and experience regarding implementation of the WHO FCTC internationally. The ICCTC is the first WHO FCTC knowledge hub in the region and the third in the world. The functions of the ICCTC include the development, analysis, synthesis, and dissemination, of knowledge and information relating to matters under its expertise, in relation to the Convention, to WHO FCTC Parties.[115]

93. Despite Uruguay's successes, however, its most vulnerable populations continue to face serious risks from tobacco use. The results of the 2009 GATS showed that smoking behavior differed by socio-economic level.[116] People from the lowest socio-economic level in Uruguay reported the highest prevalence of tobacco consumption, 35% as compared to 19.6% at the highest socio-economic levels. This inequity is a key reason behind the government's ongoing commitment to address the tobacco epidemic through tobacco control measures that satisfy its constitutional responsibility to protect the health of its citizens and its responsibilities as a PAHO Member State and a Party to the WHO FCTC.

H. FINAL STATEMENT

94. The adoption of the WHO FCTC by the World Health Assembly in 2003 and its entry into force in February 2005 had a catalytic effect on the movement of tobacco control in the Americas. There has been renewed political will to address the tobacco epidemic, with wide participation by Ministries of Health and Parliaments. Civil society also has been very active in the region, supporting governments and acting as watch-dogs regarding compliance with the WHO FCTC mandates. Uruguay has been one of the most active countries during this period, both at governmental and non-governmental levels, not only advancing its own regulations domestically but also providing support to other Member States.

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[112] Harris JE, Balsa AI, Triunfo P., *Tobacco control campaign in Uruguay: Impact on smoking cessation during pregnancy and birth effec*t. Working Paper 19878 . National Bureau of Economic Research. Cambridge MA.(January 2014).

[113] *Id.*

[114] Pan American Health Organization, *Manual for Developing Tobacco Control Legislation in the Region of the Americas, 2013*. Available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=24890&Itemid.

[115] Memorandum of Understanding between the Convention Secretariat and the Ministry of Public Health of Uruguay. Available at: http://www.who.int/fctc/implementation/cooperation/mou_uruguay/en/.

[116] World Health Organization, Global Adult Tobacco Survey (GATS) Fact Sheet, Uruguay 2009.

95. While the Americas region has seen great progress in the area of tobacco control since adoption of the WHO FCTC, protection of the region's population is far from consistent. Even though countries like Brazil, Chile, Costa Rica, Panama, Suriname and Uruguay, among others, have made significant strides, for example, barely a quarter or the population of the region is protected from the harmful effects of tobacco advertisement, promotion and sponsorship.[117]

96. As part of its technical cooperation function, PAHO continues to conduct capacity building activities to support Member States as they move to implement the WHO FCTC. Uruguay has actively participated in these events and presented its experience in areas like smoke-free environments and packaging and labeling which, as previously mentioned, are held out as examples of best practice in the region.

97. However, because of Uruguay's compliance with its Constitutional obligation to protect the health of its citizens, its obligations as a PAHO Member State, and its treaty obligations as a Party to the WHO FCTC, it is now the subject of this litigation.

98. PAHO and its Member States publicly recognize and fully support Uruguay's efforts to protect its citizens from the harmful effects of tobacco consumption, including through its implementation of the 80% Rule and the Single Presentation Rule measures and have expressed their deep concern "about misinformation campaigns and legal actions instituted by the tobacco industry against tobacco control."[118]

99. PAHO supports Uruguay's defense of the 80% Rule and the SPR, which are aimed at saving lives, and recognizes it as a role model for the Region and the world.

100. Uruguay's tobacco control measures are a reasonable and responsible response to the deceptive advertising, marketing and promotion strategies employed by the tobacco industry, they are evidence based, and they have proven effective in reducing tobacco consumption. For this simple reason, the tobacco industry is compelled to challenge them.

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[117] Pan American Health Organization/World Health Organization, Tobacco Control Report for the Region of the Americas. Washington D.C. (2013) p 1.

[118] Pan American Health Organization. 50th Directing Council. Resolution CD 50R6, *Strengthening the Capacity of Member States to Implement the Provisions and Guidelines of the WHO Framework Convention on Tobacco Control*.