

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

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AND

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CLAIMANTS

V.

**ORIENTAL REPUBLIC OF URUGUAY
RESPONDENT**

ICSID Case No. ARB/10/7

WRITTEN SUBMISSION (AMICUS CURIAE BRIEF)

BY THE

WORLD HEALTH ORGANIZATION

AND

THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL SECRETARIAT

28 JANUARY 2015

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1. Overview of Tobacco Control: History and Disease Burden

1. Tobacco consumption has negative health, social and economic implications. The importance of tobacco control to the international community is reflected in a number of international instruments, including the WHO Framework Convention on Tobacco Control (WHO FCTC)¹ and its Guidelines, the 2011 Political Declaration of the High Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases² and the WHO Global Action Plan on Prevention and Control of NCDs (2013 – 2020).³

1.1 Impacts of tobacco consumption

2. It is well established that tobacco consumption poses significant risks to human life and health and that nicotine, a core component of tobacco products, is addictive. Among other conditions, smoking causes cardio-vascular diseases such as stroke and coronary heart disease, respiratory diseases such as emphysema and chronic bronchitis, and cancers such as lung cancer.⁴ Globally, approximately 5.1 million adults aged 30 years and over die from direct tobacco use each year. In addition, some 603,000 people die from exposure to second-hand smoke every year.⁵

3. Tobacco consumption is also associated with substantial economic and social costs. As a preventable cause of disease, tobacco consumption places unnecessary burdens on already under-resourced health systems. Tobacco consumption has negative implications for sustainable economic development as it results in the diversion of household income from other expenditures such as food, health-care and education.⁶ Tobacco consumption also has substantial environmental consequences, resulting in deforestation and the decline of soil fertility where tobacco is farmed⁷, and the discard of tobacco filters and other refuse.⁸

¹ WHO Framework Convention on Tobacco Control [hereinafter “WHO FCTC”], May 21 2003, 42 ILM 518 (2003).

² Political Declaration of the High Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases, (document A/66/L.1), para. 43(c).

³ WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (resolution WHA66.10).

⁴ U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014 available at <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.

⁵ WHO Global Report: Mortality Attributable to Tobacco, World Health Organization, 2012, available at http://whqlibdoc.who.int/publications/2012/9789241564434_eng.pdf?ua=1.

⁶ See generally Prabhat Jha and Frank Chaloupka (eds) Tobacco Control in Developing Countries, Oxford University Press, (2000); Katherine Esson and Stephen Leeder, The Millennium Development Goals and Tobacco Control: An Opportunity for Global Partnership, World Health Organization, 2004.

⁷ Geist HJ. Global Assessment of Deforestation related to Tobacco Farming, 8 Tobacco Control, 1999, 18–28.

⁸ See for example, Tobacco Control, Supplement, The Environmental Burden of Cigarette Butts, May 2011, Volume 20, Suppl 1.

4. The health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke have a particularly acute impact on developing countries. This is partly because tobacco use is more prevalent among lower-income households⁹ who bear the disproportionate burden of tobacco-caused diseases and deaths. Lost income due to early death, high proportions of disposable income spent to treat tobacco-attributable diseases and money spent on tobacco use rather than other essential goods, such as food, all thwart efforts to alleviate poverty.¹⁰

5. The prevailing regulatory (rather than prohibitionist) approach to tobacco has evolved over time as public knowledge about the risks associated with tobacco products has increased. Although researchers began to link tobacco consumption with lung cancer in the late 1940's, it was not until the United States Surgeon General's Report on Smoking and Health in 1964 that the risks associated with smoking were better understood.¹¹ By this time, tobacco consumption was popular and entrenched, leading governments to pursue regulatory policies less restrictive than prohibition. These policies have also developed over time alongside understanding of risk, tobacco industry behaviour and the effects of different regulatory interventions.

1.2 International efforts to address tobacco

6. International efforts by the WHO and other actors to highlight the risks associated with tobacco consumption and to assist WHO Member States in addressing those risks have also evolved over time. This evolution reflects both the regulatory environment in which tobacco companies operate and also the increasing importance of tobacco control to public health and the international community.

1.2.1 World Health Assembly Resolutions

7. As far back as 1970 the World Health Assembly (WHA) issued a resolution concerning the Health Consequences of Smoking. This was one of 18 resolutions adopted on tobacco by the WHA¹² before adoption of the WHO FCTC in 2003. These resolutions recognize the risks associated with tobacco consumption and make recommendations with respect to the means by which WHO Member States may minimize those risks. In 2013, the WHA also adopted the WHO Global Action Plan on Prevention and Control of Noncommunicable Diseases (2013 – 2020), which

⁹ WHO, 2014. Systematic review of the link between tobacco and poverty. Available at:

http://apps.who.int/iris/bitstream/10665/136001/1/9789241507820_eng.pdf?ua=1&ua=1

¹⁰ Esson KM and Leeder SR. the Millennium Development goals and Tobacco Control: an opportunity for global partnership. WHO, 2004. Available at:

http://whqlibdoc.who.int/publications/2004/9241562870_eng.pdf?ua=1

¹¹ Smoking and Health: Report of the Advisory Committee of the Surgeon General of the Public Health Service, US Department of Health, Education and Welfare, Public Health Service, 1964.

¹² These resolutions are available at

http://www.who.int/tobacco/framework/wha_eb/wha_resolutions/en/.

includes a tobacco target aiming for a 30% relative reduction in prevalence of current tobacco use in persons aged 15 years and over.¹³

1.2.2 Current Work within the UN System

8. The importance of tobacco control to the international community is also reflected in developments within the broader UN system. In 2011, the General Assembly of the UN met for only the second time in history specifically on a health issue and shaped the global agenda on non-communicable diseases. The Political Declaration of the High Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases called upon Parties to accelerate implementation of the WHO FCTC.¹⁴ This call was repeated by the WHA in the Global Action Plan on Prevention and Control of NCDs (2013 – 2020).¹⁵

9. In August 2014 the Report of the Open Working Group of the United Nations General Assembly on Sustainable Development Goals then recommended inclusion of a goal to “[s]trengthen the implementation of the World Health Organization Framework Convention on Tobacco Control in all countries, as appropriate”.¹⁶ This report will serve as the main basis for integrating sustainable development goals into the post-2015 development agenda.

10. The United Nations (UN) Interagency Task Force on the Prevention and Control of Noncommunicable Diseases (NCDs), established by the UN Economic and Social Council in 2013, expanded the role of the UN Ad Hoc Interagency Task Force on Tobacco Control, which operated between 1999 and 2013. The Task Force coordinates the activities of the relevant UN organizations and other inter-governmental organizations to support the realization of the commitments made by Heads of State and Government in the 2011 Political Declaration on NCDs. More than 25 Agencies of the UN system as well as outside the UN system are active participants in the work of the Task Force. While the Task Force works on all aspects of NCDs, tobacco control continues to be duly addressed and prioritized.

1.3 The WHO Framework Convention on Tobacco Control

11. Following adoption by the WHA in 2003, the WHO FCTC came into force in 2005. The Convention has 180¹⁷ Parties, making it one of the most rapidly and widely embraced treaties in the UN system. Uruguay is among the Parties to the Convention and Switzerland is a signatory.

¹³ WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (resolution WHA66.10).

¹⁴ Political Declaration of the High Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases, (document A/66/L.1), para. 43(c).

¹⁵ WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (resolution WHA66.10), para. 36(a).

¹⁶ Report of the Open Working Group of the General Assembly on Sustainable Development Goals, A/68/970, para. 3(a).

¹⁷ Pending the entry into force of the Convention for Zimbabwe on 4 March 2015.

12. The WHO FCTC is an evidence-based treaty that reaffirms the right of all people to the highest standard of health. In the first paragraph of the preamble to the WHO FCTC the Parties express their determination “to give priority to their right to protect public health”. The preamble to the Convention also reflects the concerns of the international community with respect to tobacco consumption and the body of scientific evidence showing the risks associated with tobacco. Paragraphs 2-5 state:

Recognizing that the spread of the tobacco epidemic is a global problem with serious consequences for public health that calls for the widest possible international cooperation and the participation of all countries in an effective, appropriate and comprehensive international response,

Reflecting the concern of the international community about the devastating worldwide health, social, economic and environmental consequences of tobacco consumption and exposure to tobacco smoke,

Seriously concerned about the increase in the worldwide consumption and production of cigarettes and other tobacco products, particularly in developing countries, as well as about the burden this places on families, on the poor, and on national health systems,

Recognizing that scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability, and that there is a time lag between the exposure to smoking and the other uses of tobacco products and the onset of tobacco-related diseases,

13. With these concerns in mind, Article 3 of the WHO FCTC establishes the objective of the Convention in the following terms:

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

14. To achieve this objective the WHO FCTC obliges Parties to implement a number of provisions aimed at reducing demand for tobacco products, including Article 6 (price and tax measures to reduce the demand for tobacco), Article 8 (protection from exposure to tobacco smoke), Article 9 (regulation of the contents of tobacco products), Article 10 (regulation of tobacco product disclosures), Article 11 (packaging and labelling of tobacco products), Article 12 (education, communication, training and public awareness) Article 13 (tobacco advertising, promotion and sponsorship) and Article 14 (demand reduction measures concerning tobacco dependence and cessation). Although these interventions are effective alone, they are cumulative interventions that work together by targeting different drivers of tobacco consumption and different population groups as part of a complementary regulatory scheme. This is recognized in Article 5.1 of the

Convention, which requires Parties to implement comprehensive multisectoral national tobacco control strategies.

15. The WHO FCTC also obliges Parties to implement measures to reduce the supply of tobacco products, including Article 15 (illicit trade in tobacco products), Article 16 (sales to and by minors) and Article 17 (provision of support for economically viable alternative activities).

16. The Conference of the Parties to the WHO FCTC has adopted a number of instruments, including evidence-based Guidelines for the implementation of a number of provisions, such as Article 11 (packaging and labelling of tobacco products) and Article 13 (tobacco advertising, promotion and sponsorship).¹⁸ The development of the guidelines for implementation of the provisions in Articles 8 – 13 in particular was (and where relevant, continues to be) conducted in accordance with Article 7 of the WHO FCTC, which states:

The Parties recognize that comprehensive non-price measures are an effective and important means of reducing tobacco consumption. Each Party shall adopt and implement effective legislative, executive, administrative or other measures necessary to implement its obligations pursuant to Articles 8 to 13 and shall cooperate, as appropriate, with each other directly or through competent international bodies with a view to their implementation. The Conference of the Parties shall propose appropriate guidelines for the implementation of the provisions of these Articles.

Working groups comprised of representatives of Parties to the Convention drafted these and other WHO FCTC Guidelines. In drafting the guidelines, the working groups relied on available scientific evidence and the experience of the Parties themselves in implementing tobacco control measures. In each case, WHO FCTC Guidelines proposed by working groups were opened for consultation with all Parties to the WHO FCTC before being submitted to the Conference of the Parties for consideration. Each of the Guidelines has come into effect through adoption by consensus of the Conference of the Parties.

17. The status of each set of Guidelines is governed first by its wording. For example, paragraph 1 of the Guidelines on Implementation of Article 11 (packaging and labelling of tobacco products) states:

Consistent with other provisions of the WHO Framework Convention on Tobacco Control and the intentions of the Conference of the Parties to the Convention, these guidelines are intended to assist Parties in meeting their obligations under Article 11 of the Convention, and to propose measures that Parties can use to increase the effectiveness of their packaging and labelling measures. Article 11 stipulates that each Party shall adopt and implement effective packaging and labelling measures within a period of three years after entry into force of the Convention for that Party.

¹⁸ See Guidelines for Implementation of the WHO FCTC: Article 5.3; Article 8; Articles 9 and 10; Article 11; Article 12; Article 13; Article 14, WHO Framework Convention on Tobacco Control, World Health Organization, 2013 available at http://apps.who.int/iris/bitstream/10665/80510/1/9789241505185_eng.pdf?ua=1.

18. Similarly, paragraph 1 of the Guidelines on Implementation of Article 13 (tobacco advertising, promotion and sponsorship) states:

The purpose of these guidelines is to assist Parties in meeting their obligations under Article 13 of the WHO Framework Convention on Tobacco Control. They draw on the best available evidence and the experience of Parties that have successfully implemented effective measures against tobacco advertising, promotion and sponsorship. They give Parties guidance for introducing and enforcing a comprehensive ban on tobacco advertising, promotion and sponsorship or, for those Parties that are not in a position to undertake a comprehensive ban owing to their constitutions or constitutional principles, for applying restrictions on tobacco advertising, promotion and sponsorship that are as comprehensive as possible.

19. As these passages indicate, the Guidelines are intended to assist Parties in meeting their legal obligations and in increasing the effectiveness of measures adopted. The Guidelines play a particularly important role in settings where resource constraints may otherwise impede domestic policy development.

20. In addition to WHO FCTC Guidelines, and subsequent to the request for arbitration in this dispute, the Conference of the Parties to the WHO FCTC adopted the Punta del Este Declaration on Implementation of the WHO FCTC in 2010.¹⁹ In the preamble to the Declaration Parties recognize “that measures to protect public health, including measures implementing the WHO FCTC and its guidelines fall within the power of sovereign States to regulate in the public interest, which includes public health”. In the operative paragraphs of the Declaration the Parties declare, *inter alia*:

1. The firm commitment to prioritize the implementation of health measures designed to control tobacco consumption in their respective jurisdictions.
2. Their concern regarding actions taken by the tobacco industry that seek to subvert and undermine government policies on tobacco control.

...

21. The Punta del Este Declaration was adopted by consensus of the Parties and reflects their commitment to implementation of the Convention.

22. Similarly, at the Fifth Session of the Conference of the Parties to the WHO FCTC in 2012, the Parties issued the Seoul Declaration, in which they declared “[t]heir commitment to accelerate implementation of the Convention in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.”²⁰ The Sixth Session of the Conference of the Parties welcomed the Report of the Open Working Group of the United Nations General Assembly on

¹⁹ Punta del Este Declaration on Implementation of the WHO Framework Convention on Tobacco Control, Conference of the Parties to the WHO Framework Convention on Tobacco Control, fourth session, Punta del Este, Uruguay, 6 December 2010, FCTC/COP/4/DIV/6.

²⁰ Seoul Declaration, Conference of the Parties to the WHO Framework Convention on Tobacco Control, fifth session, Seoul, Republic of Korea, 17 November 2012, FCTC/COP5(5).

Sustainable Development Goals mentioned above at paragraph 9²¹ and, in the Moscow Declaration, called on Parties to accelerate the full implementation of the WHO FCTC at national levels.²²

2. Large Graphic Health Warnings: Evidence and State Practice

23. In the Request for Arbitration²³ the Claimants challenge graphic health warnings implemented by Uruguay on grounds that warnings covering 80% of the front and back of the package are excessive. The Claimants assert that warnings covering 50% of the surface of the package would be sufficient “to warn about the dangers of smoking, without destroying the ability to use established trademarks”.²⁴

24. As is set out below in further detail, the available evidence supports the conclusion that the effectiveness of health warnings increases with their prominence. Although specific studies supporting this conclusion are referred to below, this general conclusion is based on a substantial number of studies using a number of methodologies that produce consistent results across time and place. When read together, these studies comprise a body of evidence that permits generally applicable conclusions to be drawn.

2.1 Evidence concerning the effects of warnings

25. One purpose of requiring warnings on tobacco products is to inform smokers and non-smokers of the risks associated with tobacco consumption. Discouraging consumption of tobacco products is another purpose.

26. When Uruguay increased the size of its warnings from 50% to 80% of the surface of the pack there existed a considerable body of experimental and survey evidence (discussed below) suggesting that larger warnings are more legible and noticeable and, therefore, better at informing smokers and non-smokers of risk. This large body of evidence included studies in Australia and Canada concerning large graphic health warnings that supported the conclusion that 80% warnings would better serve the communication function of health warnings.

27. Findings from the 2009 Global Adult Tobacco Survey (conducted prior to the size increase and discussed below) also show that graphic health warnings in Uruguay increased the intention to quit in almost half of Uruguayan smokers. This suggests that graphic health warnings discourage tobacco consumption in Uruguay.

²¹ Towards a Stronger Contribution of the Conference of the Parties to achieving the Noncommunicable Disease Global Target on Reduction of Tobacco Use, Conference of the Parties to the WHO Framework Convention on Tobacco Control, sixth session, Moscow, Russian Federation, FCTC/COP6(16), p. 2.

²² Moscow Declaration, Conference of the Parties to the WHO Framework Convention on Tobacco Control, sixth session, Moscow, Russian Federation, FCTC/COP6(26), p. 2.

²³ Philip Morris Brands Sàrl v Oriental Republic of Uruguay (Request for Arbitration) (ICSID Arbitral Tribunal, Case No ARB/10/7, 19 February 2010) [hereinafter “Request for Arbitration”].

²⁴ *Ibid*, para. 81.

2.1.1 Informing Consumers

28. Tobacco pack warnings, and graphic warnings in particular, increase understanding of the risks associated with tobacco consumption among smokers and non-smokers alike.²⁵ Warnings increase understanding of specific risks associated with tobacco consumption, as well as understanding of the more general fact that tobacco consumption is harmful to health. The available evidence, some of which is summarised below, also suggests that health warnings perform their communication function better as their size increases.

29. Importantly, the legibility and noticeability of a health warning increases with its size. Early research on health warnings established this fact. For example, a 2001 evaluation of Australian text warnings, which at the time covered 25% and 33% of the front and back of packs respectively, supported the conclusions that increasing the size of health warnings would aid communication, and that increasing the area of the pack for messages increases legibility and noticeability.²⁶ A 2002 research report for the development of new health warnings concluded that “[a]ny increase in the font size and area of pack devoted to the message, and any contrasting background will facilitate readability.”²⁷

30. Although the fact that legibility and noticeability increases with the size of a warning was established with respect to smaller text only warnings, this fact also holds true for larger graphic warnings. For example, a 2008 review of Australian combination graphic and text warnings covering 30% of the front and 90% of the back of the pack found that the small size of the image on the front of the pack was a barrier to understanding the warnings.²⁸ Moreover, the results suggested that the 90% warning was considered the dominant image and said to generate high impact and noticeability, despite being on the back of the pack, which is less noticeable than the front.²⁹

31. Similarly, in 2008 an experimental study commissioned by Health Canada compared the status quo warnings (a text and graphic warning covering 50% of the front and back of the pack) with warnings covering 75%, 90% and 100% of the front and back respectively. The study, which examined the perceived communication impact of increasing the size of warnings, found that any of the

²⁵ For a review of the evidence see David Hammond, Health Warning Messages on Tobacco Products: A Review, 20 Tobacco Control, 2011, 327e – 337.

²⁶ Commonwealth Department of Health and Aged Care. 2001. Research report: Evaluation of the Health Warnings and Explanatory Messages on Tobacco Products. Canberra, Australia available at <http://www.who.int/entity/fctc/guidelines/ArtElevenCommonwealthEight.pdf?ua=1> pp 2, 7 & 15.

²⁷ Commonwealth Department of Health and Ageing, 2002. Developmental Research for New Australian Health Warnings on Tobacco Products Stage 1. Canberra, Australia. p.5 available at <http://www.who.int/fctc/guidelines/ArtElevenAustraliaTwentyone.pdf?ua=1>.

²⁸ Shanahan, P. and Elliott, D., Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008, Australian Government Department of Health and Ageing, Canberra, 2009, p. 12.

²⁹ *Ibid*, p.13.

three increases in size would make health warnings a more effective vehicle for communicating with adult smokers. The study also suggested that the increase in effectiveness was not linear in the sense that “each per cent of surface increase with option C (90%) and D (100%) generally delivered more impact than each percept increase from current scenario A (50%) to option B (75%).”³⁰

32. Additionally, the study suggested that increasing warning size is likely to have a greater impact on the effectiveness of health warnings than on product image (perceptions of cigarette attributes). The study examined consumer perceptions of increasing warning size on a number of issues including persuasiveness of health warnings, packaging attractiveness, and product image. Increasing the warning size was found to be more likely to affect persuasiveness and attractiveness than product image.³¹

33. The same study was conducted on Canadian youth and vulnerable non-smokers (non-smokers who say that they will probably smoke a puff or more of a cigarette over the next 12 months or who have a reason in mind that might lead them to start smoking) and the results were largely consistent with the study of adults.³² Each study found that increasing warning size from 50% to 75% would produce statistically significant but small effects on a number of indicators of effectiveness. Substantial effects on all indicators of effectiveness were achieved for warnings covering 90% of the front of the pack.³³

34. Leaving studies with respect to specific warning sizes to one side, legibility and noticeability are dependent on the conditions under which pack warnings are observed.³⁴ For example, pack warnings may be observed not only at the time of consumption, but also at the point of sale, and after the point of sale, such as when a smoker opens his or her pack. The eyesight of the viewer is another important condition, with research showing that larger warnings are particularly important for older people and those with failing eyesight.³⁵ The noticeability of messages may also vary between smokers and non-smokers. For example, in a 1999 review of Canadian pack warnings non-smokers were more likely to think that increasing the

³⁰ Les Études De Marché Créatec, Quantitative Study Of Canadian Adult Smokers Effects Of Modified Packaging Through Increasing the Size of Warnings on Cigarette Packages, Prepared for Health Canada, April 2008, p.4.

³¹ *Ibid.*

³² Les Études De Marché Créatec, Quantitative Study of Canadian Youth Smokers and Vulnerable Non-Smokers: Effects of Modified Packaging Through Increasing the Size of Warnings on Cigarette Packages, Prepared for Health Canada, April 2008.

³³ Les Études De Marché Créatec, Quantitative Study Of Canadian Adult Smokers Effects Of Modified Packaging Through Increasing the Size of Warnings on Cigarette Packages, Prepared for Health Canada, April 2008, p.5.

³⁴ Wogalter MS, Conzola VC, Smith-Jackson TL, 2002. Research Based Guidelines for Warning Design and Evaluation, 33(3) Applied Ergonomics, 2002, 219-230.

³⁵ Commonwealth Department of Health and Aged Care. 2001. Research report: Evaluation of the Health Warnings and Explanatory Messages on Tobacco Products. Canberra, Australia. available at <http://www.who.int/entity/ftc/guidelines/ArtElevenCommonwealthEight.pdf?ua=1> p. 7.

size of warnings would make them more noticeable.³⁶ This suggests that the size of a warning may in some cases be relatively more important for informing non-smokers than for smokers who are exposed to the warnings at closer range and greater frequency.

35. It is also important to recognize that a general awareness among the population that smoking is harmful to health cannot be equated with consumers fully understanding the risks they are undertaking, or having knowledge of specific risks.³⁷ The 2009 Global Adult Tobacco Survey provides evidence specific to Uruguay on this point.

36. The Global Adult Tobacco Survey (GATS) is conducted by the WHO and the United States Centers for Disease Control and Prevention in collaboration with selected WHO Member States. GATS is the global standard to monitor systematically adult tobacco use and track key tobacco indicators. GATS is intended to generate comparable data within and across countries. It enhances countries' capacity to design, implement and evaluate tobacco control interventions. GATS has been conducted in 21 countries, including Uruguay, representing 60% of the world's population and approximately 40% of cigarette smokers globally.

37. This nationally representative GATS household survey was undertaken in Uruguay with 5581 interviews conducted prior to the increase in pack warning size from 50% to 80% and was structured so as to provide a nationally representative sample. 97.6% of respondents in Uruguay believed that smoking causes serious illness. However, only 76.5% of respondents believed that smoking causes cerebrovascular stroke and only 63.7% of 15-24 year olds believed that smoking causes stroke.³⁸ Additionally, among those adults who identified smoking as harmful 19.2% were unaware that light, ultra light or mild cigarettes are as harmful as regular cigarettes. The survey also found that 20.3% of the same group was unaware that mentholated cigarettes are as harmful as regular cigarettes.³⁹

38. In addition to affecting legibility and noticeability, the size of warnings may affect the ability of smokers and non-smokers to recall specific health warnings. Early research on the size and placement of warnings supports the conclusion that larger text warnings placed on the front of the pack were more likely to be recalled

³⁶ Canadian Adult and Youth Opinions on the Sizing of Health Warning Messages, Prepared for Health Canada Office for Tobacco Control, October 1999, Prepared by Environics Research Group, p. 33.

³⁷ Hammond, D., G. T. Fong, A. McNeill, R. Borland, and K. M. Cummings, "Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey," 15 Tobacco Control, 2006, iii19-iii25.

³⁸ Global Adult Tobacco Survey (GATS): Uruguay Country Report 2011, available at <http://nccd.cdc.gov/gtssdata/Ancillary/DataReports.aspx?CAID=3>, p. 153 table 9.1.

³⁹ *Ibid*, p. 155 table 9.3.

than smaller warnings and warnings placed on panels other than the front of the pack.⁴⁰

2.1.2. Discouraging Consumption

39. Assessing the impact of tobacco pack warnings on the prevalence of tobacco use or on total consumption is methodologically challenging for two primary reasons. First, unlike some other tobacco control measures such as taxes, changes to pack warnings are unlikely to cause a sudden drop in the prevalence of tobacco consumption. Rather, changes to existing warnings are more likely to affect the knowledge of non-smokers, thereby slowing the uptake of smoking gradually. Second, it is difficult to control for other variables that may affect the prevalence of tobacco use, or total consumption. For example, there are often difficulties controlling for the impacts of other tobacco control measures, whether they are pre-existing or new.

40. Nonetheless, quantitative models suggest that health warnings do reduce the prevalence of tobacco consumption.⁴¹ There is also evidence of the impact of pack warnings on smokers. This evidence shows that warnings increase the intention of smokers to quit. For example, in Uruguay the 2009 Global Adult Tobacco Survey found that 44.6% of smokers thought about quitting because of a warning label. Although not all thoughts of quitting translate into action, thinking of quitting is a precursor to action. Moreover, the conclusion that increasing the size of large graphic warnings decreases the prevalence of tobacco use or total consumption is consistent with the broader body of empirical research on tobacco warning labels.

2.2 Relevant provisions of the WHO FCTC and Guidelines for implementation

41. The WHO FCTC includes a number of obligations relevant to the size of tobacco pack warnings and to the development of such warnings, and the relevant Guidelines for its implementation propose measures to assist Parties in meeting these obligations. These provisions demonstrate the international consensus surrounding the evidence discussed in section 2.1.

42. Article 4 of the WHO FCTC establishes guiding principles. Article 4.1 states that:

Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke.

⁴⁰ See for example Environics Research Group. Testing New Health Warning Messages for Cigarette Packages: A Summary of Three Phases of Focus Group Research: Final Report. (Prepared for Health Canada), Ottawa, Health Canada, 2000 available at <http://legacy.library.ucsf.edu/tid/irl70g00/pdf>.

⁴¹ David T Levy, Jennifer A Ellis, Darren Mays & An-Tsun Huang, Smoking-Related Deaths Averted due to Three Years of Policy Progress, 91 Bulletin of the World Health Organization, 2013, 509-518.

43. Tobacco packaging and labelling measures provide one means by which consumers are informed of these risks. Article 11 of the Convention sets out more specific obligations with respect to packaging and labelling measures. Health warnings are governed by Article 11.1(b), which states:

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:

...

(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, and may include other appropriate messages. These warnings and messages:

- (i) shall 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,
- (v) may be in the form of or include pictures or pictograms.

44. As stated above, Guidelines for Implementation of Article 11 “are intended to assist Parties in meeting their obligations under Article 11 of the Convention, and to propose measures that Parties can use to increase the effectiveness of their packaging and labelling measures.”⁴² The Guidelines establish a number of “principles”, in which Parties to the WHO FCTC have, by consensus, recognized that well designed warnings increase public awareness of the health risks and are effective in reducing tobacco consumption. Paragraph 3 states:

Globally, many people are not fully aware of, misunderstand or underestimate the risks for morbidity and premature mortality due to tobacco use and exposure to tobacco smoke. Well designed health warnings and messages on tobacco product packages have been shown to be a cost-effective means to increase public awareness of the health effects of tobacco use and to be effective in reducing tobacco consumption. Effective health warnings and messages and other tobacco product packaging and labelling measures are key components of a comprehensive, integrated approach to tobacco control.

45. The Guidelines also provide guidance on “developing effective packaging and labelling requirements”. In paragraph 7, Parties again recognize the evidence base underlying health warnings and the approaches that are most likely to be effective.

Well-designed health warnings and messages are part of a range of effective measures to communicate health risks and to reduce tobacco use. Evidence demonstrates that the effectiveness of health warnings and messages increases with their prominence. In comparison with small, text only health warnings, larger warnings with pictures are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption. Larger picture warnings are also more likely to retain their effectiveness over time and are particularly effective

⁴² Guidelines for Implementation of Article 11, para. 1.

in communicating health effects to low-literacy populations, children and young people. Other elements that enhance effectiveness include locating health warnings and messages on principal display areas, and at the top of these principal display areas; the use of colour rather than just black and white; requiring that multiple health warnings and messages appear concurrently; and periodic revision of health warnings and messages.

46. The Guidelines also provide more specific guidance with respect to the size of health warnings. Most notably, the Parties recognize that the effectiveness of health warnings increases with their size. Paragraph 12 states:

Article 11.1(b)(iv) of the Convention specifies that health warnings and messages on tobacco product packaging and labelling should be 50% or more, but no less than 30%, of the principal display areas. 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. The text of health warnings and messages should be in bold print in an easily legible font size and in a specified style and colour(s) that enhance overall visibility and legibility.

47. The Guidelines indicate that pre-marketing testing of warnings by individual Parties is desirable, but by no means a necessity for development of effective pack warnings.⁴³ In this respect, these evidence-based Guidelines constitute a resource for Parties to rely upon in developing their warnings. The ability of Parties to rely on this evidence-based resource in policy development is important for implementation of the Convention by all Parties, and particularly by Parties in low resource settings.

48. The Guidelines also recognize that health warnings require review. The Guidelines state that “[l]egal measures should be reviewed periodically and updated as new evidence emerges and as specific health warnings and messages wear out.”⁴⁴ Examples of this are set out below in paragraph 2.3.2.

49. Finally, it is important to recognize that the Guidelines are evidence-based. In the case of the Guidelines for Implementation of Article 11, the reference material used in their development has been released publicly.⁴⁵ Where relevant, this material has been referred to in this brief in conjunction with additional evidence.

2.3 State Practice

50. A substantial number of states (including the Claimant’s home state) compel the presence of warnings on tobacco products that take up on average more than 50% of the front and back of tobacco packages. A substantial number of states also either require warnings that take up more than 50% of the front of the pack, or are in the process of implementing laws requiring such warnings. Uruguay’s approach of moving from text to a combination of text and graphic warnings, and of increasing the size of graphic warnings over time, is also consistent with state practice.

⁴³ *Ibid*, paras 39 – 40.

⁴⁴ *Ibid* para. 60.

⁴⁵ See <http://www.who.int/fctc/guidelines/adopted/eleven/en/>.

2.3.1 State practice with respect to the size of health warnings

51. Laws requiring warnings covering on average more than 50% of the front and back of a pack have been implemented in 18 states, including Uruguay. These states are:

- Thailand (85% of the front and back);⁴⁶
- Australia (75% of the front and 90% of the back);⁴⁷
- Brunei (75% of the front and back);⁴⁸
- Canada (75% of the front and back);⁴⁹
- Nepal (75% of the front and back);⁵⁰
- Mauritius (60% of the front and 70% of the back);⁵¹
- Mexico (30% of the front and 100% of the back);⁵²
- Ecuador (60% of the front and back);⁵³
- New Zealand (30% of the front and 90% of the back);⁵⁴
- Fiji (30% of the front and 90% of the back);⁵⁵
- Belgium (48% of the front and 63% of the back, including the border);⁵⁶
- Switzerland (48% of the front and 63% of the back, including the border);⁵⁷
- Liechtenstein (48% of the front and 63% of the back, including the border);⁵⁸
- Turkey (65% of the front and 43% of the back, including the border);⁵⁹
- Finland (45% of the front and 58% of the back, including the border);⁶⁰

⁴⁶ Notice of Rules, Procedures, and Conditions for the Display of Images, Warning Statements, and Contact Channels for Smoking Cessation on Cigarette Labels, Vol. 130, Special Section, 45 D, The Government Gazette, 5 April 2013 .

⁴⁷ Competition and Consumer (Tobacco) Information Standard 2011, to the Competition and Consumer Act 2010 (Cth).

⁴⁸ Tobacco (Labelling) (Amendment) Regulations, 2012.

⁴⁹ Tobacco Products Labelling Regulations (cigarettes and little cigars) (SOR/2011-177) pursuant to the Tobacco Act (S.C. 1997, c. 13).

⁵⁰ Tobacco Products (Control and Regularization) Regulation – 2068 [2011 AD] to the Tobacco Product (Control and Regulation) Act 2011).

⁵¹ Public Health (Restrictions on Tobacco Products) (Amendment) Regulations 2009

⁵² General Law for Tobacco Control (published in the Official Gazette on May 30, 2008, available at http://www.who.int/fctc/reporting/party_reports/mexico_annex5_general_tobacco_law.pdf?ua=1

⁵³ Organic Law for the Regulation and Control of Tobacco, Official Gazette No. 497 – Friday, July 22, 2011 – 3.

⁵⁴ Smoke-free Environments Regulations 2007 (SR 2007/39) (as amended) pursuant to the Smoke-free Environments Act 1990.

⁵⁵ Tobacco Control Decree 2010 (Decree No. 63 of 2010), available at [http://www.fiji.gov.fj/getattachment/be952f5d-ea55-44ee-a369-bdf16c19081f/Decree-No-63---Tobacco-Control-Decree-2010-\(pdf\).aspx](http://www.fiji.gov.fj/getattachment/be952f5d-ea55-44ee-a369-bdf16c19081f/Decree-No-63---Tobacco-Control-Decree-2010-(pdf).aspx).

⁵⁶ Royal Decree of 13 August 1990 on the Manufacture and Marketing of Tobacco- based and Similar Products (as amended through 2009).

⁵⁷ Ordinance of the Federal Department of Home Affairs on Combined Warnings on Tobacco Products, 2007.

⁵⁸ Proclamation of April 29, 2014, Swiss Customs Law Applicable to Liechtenstein by Virtue of the Customs Treaty, Appendices I and II, s 817.064 available at https://www.gesetze.li/get_pdf.jsp?PDF=2014116.pdf.

⁵⁹ Tobacco & Alcohol Market Coordination Committee's (TAPDK) Decision No. 4721 (2009) unofficial translation available at <http://www.tobaccocontrollaws.org/files/live/Turkey/Turkey%20-%20Decision%20No.%204721.pdf>.

- Ireland (45% of the front and 58% of the back)⁶¹ and
- the Kyrgyz Republic (52% of the front and back, including the border).⁶²

52. In addition, such laws have been passed and are under implementation in another 30 states. These states include the 28 Member States of the European Union (which includes Belgium, Finland and Ireland) (65% of the front and back of the pack),⁶³ Sri Lanka (60% of the front and back)⁶⁴ and India (85% of the front and back).⁶⁵ Larger warnings are also under implementation in Nepal (increasing from 75% to 90% of the front and back).⁶⁶ Once these laws are implemented, at least 44 states will require combination graphic and text warnings covering on average more than 50% of the pack.

53. As these figures indicate, in addition to a substantial number of states requiring warnings that *on average* take up more than 50% of the front and back of the pack, nine states other than Uruguay require warnings that take up more than 50% of the front of the pack and 30 states are in the process of implementing such laws. The laws increasing these warning sizes in each of the 39 states in question have been passed since 2009. Accordingly, Uruguay is one of a substantial number of states that in recent history has either passed or implemented laws requiring warnings larger than 50%.

2.3.2 State practice of changing health warning requirements over time

54. Many states, including Uruguay, have changed their health warning laws over time. States have moved from requiring textual to combination graphic and text warnings and have increased the size of the warnings required. Examples include Australia, Canada, the Member States of the European Union and Thailand. This practice is consistent with research suggesting that changes in health warnings increase their effectiveness.⁶⁷

⁶⁰ Decree of the Ministry of Social Affairs and Health on Labelling the Unit Packets of Tobacco Products, on Maximum Yields of and Methods for Measuring Harmful Substances, and on Testing Laboratories, 2002.

⁶¹ Public Health (Tobacco) (General and Combined Warnings) Regulations 2011.

⁶² The law of Kyrgyz Republic "on Protection of Health of Citizens of Kyrgyz Republic against Harmful Tobacco Impact", (2006) available at http://www.who.int/fctc/reporting/Kyrgyzstan_annex4_tobacco_act2006_en.pdf.

⁶³ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning the Manufacture, Presentation and Sale of Tobacco and related Products and repealing Directive 2001/37/EC.

⁶⁴ Regulation Amending The Tobacco Products Labelling and Packaging Regulations, No. 1 of 2012, 2014.

⁶⁵ Cigarettes and other Tobacco Products (Packaging and Labelling) Amendment Rules, 2014.

⁶⁶ Directives for Printing and Labeling of Warning Message and Graphics in the Boxes, Packets, Wrappers, Cartons, Parcels and Packaging of Tobacco Products - 2071 [2015]

⁶⁷ Hammond, David, Geoffrey T. Fong, Ron Borland, K. Michael Cummings, Ann McNeill, and Pete Driezen, Text and Graphic Warnings on Cigarette Packages, 32(3) American Journal of Preventive Medicine, 2007, 202-09

55. Australian state laws, in 1985, required text only warnings covering 15% of the front and back of the pack.⁶⁸ A 1994 Regulation increased the size of the warnings to 25% of the front of the pack and 33% of the back.⁶⁹ A 2004 Regulation required a graphic and text warning covering 30% of the front and 90% of the back.⁷⁰ A 2011 Standard now requires warnings covering 75% and 90% of the front and back respectively.⁷¹

56. Canada, in 1989, required text only warnings covering 20% of the front and back of the pack.⁷² In 1994, the size of these warnings was increased to 35%.⁷³ A 2000 regulation required a graphic and text warning covering 50% of the front and back of the pack.⁷⁴ In 2011, the size of these warnings was increased to 75% of the front and back of the pack.⁷⁵

57. Thailand, in 1992, required text only warnings covering 25% of the surface of the pack.⁷⁶ In 2009, the Ministry of Public Health issued a Notification requiring a graphic and text warning covering 55% of the front and back of the pack.⁷⁷ In 2013, this requirement was increased to require warnings covering 85% of the front and back of the pack.⁷⁸

58. In the case of the EU Member States, a 2001 EC Directive required textual warnings covering not less than 30% of the front and not less than 40% of the back of the pack.⁷⁹ This Directive also required the European Commission to develop a database of graphic warnings, the purpose of which was to harmonize use of graphic warnings for those Member States choosing to go above and beyond the text

⁶⁸ See <http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-warn>.

⁶⁹ Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 1994.

⁷⁰ Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004.

⁷¹ Competition and Consumer (Tobacco) Information Standard 2011, to the Competition and Consumer Act 2010.

⁷² Bill C – 51 Tobacco Products Control Act, 1988.

⁷³ Labeling Regulations Amendment to the Tobacco Products Control Act, 1994.

⁷⁴ Tobacco Products Information Regulations, 2000, pursuant to the Tobacco Act.

⁷⁵ Tobacco Products Labelling Regulations (cigarettes and little cigars) (SOR/2011-177) pursuant to the Tobacco Act (S.C. 1997, c. 13).

⁷⁶ Tobacco Products Control Act, B.E. 2535 (1992); Notification of the Ministry of Public Health (No. 13) 2550 (A.D. 2007) Re: Criteria, Procedures and Conditions for Displaying Pictorial Labels and Statements of Warning on Harm of Cigars Issued under the Tobacco Products Control Act B.E. 2535 (A.D. 1992).

⁷⁷ Ministry of Public Health Notice of Rules, Procedures, and Conditions for the Display and Content of Cigarette Labels, 2009, Vol. 126, Special Section 143 D The Government Gazette, 30 September 2009.

⁷⁸ Ministry of Public Health Notice Of Rules, Procedures, and Conditions for the Display of Images, Warning Statements, and Contact Channels for Smoking Cessation on Cigarette Labels, 2013, Vol. 1, 30, Special Section 45 D, The Government Gazette, 5 April 2013.

⁷⁹ Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning the Manufacture, Presentation and Sale of Tobacco Products, Commission Statement, Official Journal L 194 , 18/07/2001 P. 0026 – 0035.

warning. A 2003 European Commission Decision established that database.⁸⁰ More recently, the 2014 Tobacco Products Directive will require graphic and text warnings covering at least 65% of the front and back of the pack in all 28 EU Member States.⁸¹

59. These examples of state practice show how the development of health warnings in Uruguay is consistent with their development in other states at the forefront of tobacco control. These examples also illustrate a regulatory approach whereby states increase the size of warnings over time. In addition to addressing the fact that consumers underestimate the risks associated with tobacco consumption (discussed at para. 37), increasing the size of warnings addresses concerns about the impact of health warnings declining over time.

2.3.3 Reasons for variation in the size and content of health warnings among states

60. As the examples of state practice above illustrate, there is no single accepted approach with respect to the size of health warnings. Rather, there is some variation in the approaches taken. This variation has at least three explanations.

61. First, although the evidence with respect to warnings is generally applicable, warnings have slightly different effects among different population groups, and can vary across the territory of WHO Member States for this reason.

62. Second, sovereign states adopt different levels of protection with respect to the risks associated with tobacco consumption. Social and cultural factors, including the political economy of tobacco control, shape the extent to which individual states protect against the risks associated with tobacco products. These differences in risk tolerance are reflected in variation with respect to implementation of tobacco control measures, including warnings.

63. Third, in accordance with the approach set out in the WHO FCTC, health warnings are one of a number of tobacco control measures implemented to address the risks associated with tobacco consumption. Other types of measures which Parties to the WHO FCTC are required to implement include tax and price measures (Article 6), measures to protect third parties from exposure to tobacco smoke (Article 8), regulating the content of tobacco products and product disclosures (Articles 9 and 10), education, communication, training and public awareness campaigns (Article 12), restrictions on advertising, promotion and sponsorship (Article 13) and demand reduction measures concerning tobacco dependence and

⁸⁰ Commission Decision of 5 September 2003 on the use of Colour Photographs or other Illustrations as Health Warnings on Tobacco Packages (notified under document number C(2003) 3184) (Text with EEA relevance) (2003/641/EC).

⁸¹ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning the Manufacture, Presentation and Sale of Tobacco and Related Products and repealing Directive 2001/37/EC [hereinafter "Directive 2014/40/EU"].

cessation. Each of these measures has different effects and when used together the measures form a comprehensive regulatory regime. In this context, variation among health warnings is explained partly by the fact that sovereign states place different emphasis on one approach or another.

3. The Prohibition on Misleading Packaging

64. As is set out below in section 3.1, it is well established that descriptors such as “low tar”, “light”, “ultra light” and “mild” are misleading when used in association with tobacco products. These and other descriptors suggest that products with which they are associated are less harmful to health than the regular variant of a brand when, in fact, the evidence contradicts this conclusion. The effect of misleading branding is to discourage existing smokers from quitting and to encourage non-smokers to take up the habit, a fact recognized by tobacco companies.⁸² In the Uruguayan context, the 2009 Global Adult Tobacco Survey demonstrated that a significant proportion of Uruguayans were unaware that light, ultra light, mild or menthol cigarettes were as harmful as regular cigarettes.⁸³

65. As described below in section 3.2, the presence of colours and other design elements on packaging can affect consumer perceptions of the harmfulness of tobacco products. This has perpetuated the misleading character of some tobacco brands after the prohibition of misleading descriptors because consumers continue to associate design elements including package colours with banned deceptive descriptors. In this respect, there is evidence from countries other than Uruguay that consumers are adept at recognizing which colour packages are associated with prohibited descriptors.⁸⁴

66. As is set out in section 3.2 the WHO FCTC obliges Parties to prohibit misleading tobacco packaging and labelling⁸⁵ and Guidelines to the Convention recognize explicitly that colours may be misleading.⁸⁶ Although Uruguay is the only Party to have prohibited brand extensions on grounds that they are misleading, the rationale for this action is supported by the evidence. With respect to state practice, it is not uncommon for states to prohibit specific categories of tobacco products. Indeed, a number of states have prohibited brand extensions in the form of flavoured tobacco products.⁸⁷

⁸² On each of these points see the discussion below and Monograph 13: Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine, US Department Of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, 2001, chapter 6.

⁸³ Global Adult Tobacco Survey Uruguay 2009, p. 155 table 9.3.

⁸⁴ Gregory N Connolly and Hillel R Alpert, Has the Tobacco Industry Evaded the FDA's Ban on 'Light' Cigarette Descriptors? 23 Tobacco Control, 2014, 140 – 145.

⁸⁵ WHO FCTC, Article 11.

⁸⁶ WHO FCTC Guidelines for Implementation of Article 13, para. 39, fn. 7.

⁸⁷ For example, in the United States see Family Smoking Prevention and Tobacco Control Act, HR 1256, section 907(a)(1)(A).

3.1 Light, Ultra Light and similar Brand Variants Mislead Consumers with respect to Harmfulness

67. In 1966, the United States Federal Trade Commission (FTC) permitted tobacco companies to advertise tar and nicotine yields of different products provided that the companies used a standard machine testing method adopted by the FTC. Tobacco companies often used the tar and nicotine yields as a basis for and in association with descriptors such as light, ultra light and mild.⁸⁸

68. It was not publicly understood until much later that the machine testing method used by the FTC was flawed in a number of ways. The machine testing method did not replicate human behaviour partly because smokers compensated for lower tar and nicotine yields by taking larger puffs and taking more puffs of a cigarette. The machine testing method also failed to account for the presence of holes in cigarette filters, some of which were blocked by smokers' fingers during the act of smoking. Accordingly, the evidence available today is overwhelming to the effect that low tar, low nicotine, light, ultra light, mild and similar brand variants are no less harmful to health than "regular" or original brand variants.⁸⁹

69. This conclusion finds additional support in domestic court findings in the United States. In an action brought by the US government under the Racketeer Influenced and Corrupt Organizations Act (RICO), the US District Court for the District of Columbia found *inter alia* that light, low tar and similar cigarettes offer no clear health benefit over regular cigarettes and the US FTC testing method does not measure actual tar and nicotine delivery.⁹⁰

70. With this in mind, light, ultra light and similar brand variants are misleading because they suggest that the products with which they are associated are less harmful to health than regular brand variants. Survey evidence from Uruguay and other states, as well as the abovementioned US domestic court findings, show that consumers believe these variants to be less harmful.

71. The 2009 GATS found that among those Uruguayan adults who identified smoking as harmful 19.2% were unaware that light, ultra light or mild cigarettes are as harmful as regular cigarettes.⁹¹

⁸⁸ R W Pollay and T Dewhirst, The Dark Side of Marketing Seemingly "Light" Cigarettes: Successful Images and Failed Fact, 11 (Suppl 1) Tobacco Control, 2002, i18-i31.

⁸⁹ Monograph 13: Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine, US Department Of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, 2001; SACTOB Conclusions on Health Claims Derived from ISO/FTC Method to Measure Cigarette Yield, World Health Organization, 2003.

⁹⁰ *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in part & vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam), *cert. denied*, 561 U.S. ___, 130 S. Ct. 3501 (2010), pp 740 - 817.

⁹¹ Global Adult Tobacco Survey (GATS): Uruguay Country Report 2011, available at <http://nccd.cdc.gov/gtssdata/Ancillary/DataReports.aspx?CAID=3>, p. 155 table 9.3.

72. The results of the 2009 Uruguay GATS are also consistent with studies conducted in other countries. For example, the 2009 GATS found that 21.9% of respondents in the Russian Federation believed that some cigarettes may be less harmful than others.⁹² Similarly, in a separate study published in 2008, respondents to a four-country survey in Australia, Canada, the United Kingdom (UK) and US were asked to respond to the incorrect propositions that “(1) light cigarettes are less harmful than regular cigarettes, (2) smokers of light cigarettes take in less tar than smokers of regular cigarettes and (3) light cigarettes make it easier to quit smoking.” Approximately 50% of respondents in each of these states agreed with at least one of these incorrect propositions.⁹³ This survey was conducted in four waves to assess the impact of a ban on misleading descriptors in the UK. In the first wave 69.5% of respondents in the UK endorsed at least one of the incorrect propositions. In the fourth and final wave, approximately two years after the ban went into effect, 58% of respondents still endorsed at least one of the three incorrect propositions.⁹⁴

73. Another study conducted as part of the same four-country survey and published in 2011 found that approximately 20% of respondents (across the four countries) believed incorrectly that some cigarette brands could be less harmful than others. This conclusion was notwithstanding the fact that use of misleading terms such as light and mild were prohibited in the countries in question.⁹⁵

74. The US District Court for the District of Columbia also concluded that light, ultra light and similar brand variants are misleading in the RICO action cited at paragraph 69. The court found that tobacco companies recognized that smokers switch to light / low tar cigarettes rather than quit smoking because they believe they are less harmful.⁹⁶

75. The surveys identified in paragraphs 72 and 73 also demonstrate that false beliefs about the harmfulness of light, ultra light and similar products persist and are widespread despite bans on the use of misleading descriptors and the public education campaigns implemented alongside them. In the case of Uruguay, these beliefs persisted in 2009 at the time of the Global Adult Tobacco Survey.

76. Finally, it is important to note that these conclusions about the misleading character of some branding also apply to menthol-flavoured cigarettes. Menthol

⁹² Global Adult Tobacco Survey (GATS): Russian Federation 2009 Country Report, available at http://www.who.int/tobacco/surveillance/en_tfi_gats_russian_countryreport.pdf?ua=1 p. 68.

⁹³ R Borland *et al*, What happened to Smokers’ Beliefs about Light Cigarettes when “Light/Mild” Brand Descriptors were Banned in the UK? Findings from the International Tobacco Control (ITC) Four Country Survey, 17 Tobacco Control, 2008, 256 – 262.

⁹⁴ *Ibid.* p. 258.

⁹⁵ Seema Mutti, David Hammond, Ron Borland, Michael K. Cummings, Richard J. O’Connor & Geoffrey T. Fong, ‘Beyond Light and Mild: Cigarette Brand Descriptors and Perceptions of Risk in the International Tobacco Control (ITC) Four Country Survey, 106(6) Addiction, Jun 2011, 1166-75.

⁹⁶ *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff’d in part & vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam), *cert. denied*, 561 U.S. ___, 130 S. Ct. 3501 (2010), pp 819 – 864.

soothes the smoker's throat and descriptors such as the term "fresh" connote healthfulness.⁹⁷ In this respect, the 2009 Global Adult Tobacco Survey found that 20.3% of Uruguayan adults who identified smoking as harmful were unaware that mentholated cigarettes are as harmful as regular cigarettes.⁹⁸

3.2 Brand Variants can Perpetuate the Deception associated with Light, Ultra Light and Similar Products

77. Brand variants can perpetuate the deception associated with light, ultra light and similar variants in at least two ways.

78. First, colours and other design elements have been used to preserve misleading brand extensions. Evidence of this comes from a number of sources, including the United States where an Altria brochure, concerning Philip Morris USA products was distributed to retailers.⁹⁹ That brochure showed the new pack identifiers associated with misleading brand variants and enabled retailers to assist consumers in identifying those variants after misleading descriptors were removed from packaging. For example, Marlboro Lights became Marlboro Gold and Marlboro Ultra Lights became Marlboro Silver. The brochure also indicated that "some cigarette and smokeless packaging is changing, but the product stays the same". In this context, a nationally representative survey of US smokers conducted one year after the ban on misleading descriptors came into effect found that 92% of smokers reported that they could easily identify their usual brands and 68% correctly named the package colour associated with their usual brand.¹⁰⁰

79. Second, brand extensions can in themselves be misleading to consumers, particularly when presented in the course of trade alongside one another and regular or full flavoured brands. One reason for this is that people try to find attributes among brand variants.¹⁰¹ Another reason is that packaging, and particularly colour, affect consumers' perceptions of risk. Early evidence of this can be found in internal tobacco industry documents released to the public through litigation. For example, a 1990 tobacco industry document recognized that so-called

⁹⁷ See Anderson SJ, Marketing of Menthol Cigarettes and Consumer Perceptions: A Review of Tobacco Industry Documents, 20(Suppl 2) Tobacco Control, May 2011, ii20-ii28; Anderson SJ, Menthol Cigarettes and Smoking Cessation Behaviour: A Review of Tobacco Industry Documents, 20(Suppl 2) Tobacco Control, May 2011, ii49-ii56.

⁹⁸ Global Adult Tobacco Survey (GATS): Uruguay Country Report 2011, available at <http://nccd.cdc.gov/gtssdata/Ancillary/DataReports.aspx?CAID=3>, p. 155 table 9.3.

⁹⁹ Philip Morris, Retailer Brochure. Introducing New Packaging on many Philip Morris USA (PM USA) Brands. 2010. Bates Number 5003355067-5072 available in colour at <http://www.nacsonline.com/News/Daily/Documents/AltriaBrochure.pdf> and on the Philip Morris website at <http://www.pmdocs.com/core/downloadSearchBlob?IDX=1&FROM=SEARCH&CVSID=34e3d36b9412b753adc386cd5630b887>.

¹⁰⁰ Gregory N Connolly and Hillel R Alpert, Has the Tobacco Industry Evaded the FDA's Ban on 'Light' Cigarette Descriptors? 23 Tobacco Control, 2014, 140 – 145.

¹⁰¹ Ron Borland and Steven Savvas, The Effects of Variant Descriptors on the Potential Effectiveness of Plain Packaging, 23 Tobacco Control, 2014, 58–63.

“lower delivery products” were featured in lighter packs because they have a clean healthy connotation.¹⁰²

80. This observation is consistent with other internal tobacco industry documents, including studies that tested consumer reactions to ultra light products packaged in different colour packs.¹⁰³ These reactions included consumers ranking the perceived tar level of products in different colour packs¹⁰⁴ and commenting on factors such as the harshness and strength of the flavour of different colour packs with otherwise identical products inside them.¹⁰⁵

81. The broader observation that pack design affects consumer perceptions of risk is also consistent with subsequent peer-reviewed studies that document the association between packaging and risk perception in countries other than Uruguay.¹⁰⁶ Taken together, the internal industry documents and peer-reviewed studies suggest that even in the absence of prior misleading descriptors, brand extensions can create misleading perceptions concerning the relative risks of brand variants.

3.3 Relevant provisions of the WHO FCTC and Guidelines for implementation

82. Article 11.1(a) of the WHO FCTC obliges Parties to prohibit misleading tobacco packaging and labelling. The provision states:

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:

(a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous

¹⁰² Philip Morris, Marketing New Products in a Restrictive Environment; 1990 June Report Bates No 2044762173-2364. The document states “Lower delivery products tend to be featured in blue packs. Indeed, as one moves down the delivery sector, then the closer to white a pack tends to become. This is because white is generally held to convey a clean healthy association.”

¹⁰³ See generally M Wakefield, C Morley, JK Horan and KM Cummings, The Cigarette Pack as Image: New Evidence from Tobacco Industry Documents, 11 (Suppl 1) Tobacco Control, 2002, i73-i80.

¹⁰⁴ Philip Morris, Marketing Research Department Report Marlboro Ultra Light Pack Study: Top-Line Results, February 9, 1981, Bates no. 2048718182-2048718194 available at <http://www.legacy.library.ucsf.edu/tid/fpc36e00;jsessionid=03C8192F212A226CB9A1B89760F0D162.tobacco01>.

¹⁰⁵ Philip Morris, Identified HTI Test Of Marlboro Ultra Lights In A Blue Pack Versus Marlboro Ultra Lights In A Red Pack (Project No. 1256/1257), September 3, 1996, Bates no. 2047387079-2047387089, available at <http://www.legacy.library.ucsf.edu/tid/geb36e00/>.

¹⁰⁶ David Hammond and Carla Parkinson, The Impact of Cigarette Package Design on Perceptions of Risk, 31(3) Journal of Public Health, September 2009, 345-53; David Hammond, Martin Dockrell, Deborah Arnott, Alex Lee, Ann McNeill, Cigarette Pack Design and Perceptions of Risk Among UK Adults and Youth, 19(6) European Journal of Public Health, 2009, 631 – 637; Maansi Bansal-Travers, David Hammond, Philip Smith, K. Michael Cummings, The Impact of Cigarette Pack Design, Descriptors, and Warning Labels on Risk Perception in the US, 40(6) American Journal of Preventive Medicine, 2011, 674 – 682.

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”;

83. The Guidelines for Implementation of Article 11 stress that the terms included in Article 11.1(a) are indicative of misleading terms, but that the list is not exhaustive.¹⁰⁷

84. The obligation to prevent misleading conduct is also not limited to terms, descriptors, trademarks and figurative or any other signs. Article 13 of the WHO FCTC obliges Parties to prohibit misleading tobacco advertising, promotion or sponsorship. Pursuant to Article 1(c) the phrase ““tobacco advertising and promotion” means 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.” The relevant provisions of Article 13 state:

1. Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products.
2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship.
...
4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:
 - (a) 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;
...

85. In Guidelines for Implementation of Article 13 Parties have also recognized that various types of branding may be misleading. Paragraph 39 states:

Parties should prohibit the use of any term, descriptor, trademark, emblem, marketing image, logo, colour and figurative or any other sign [footnote omitted] that promotes a tobacco product or tobacco use, whether directly or indirectly, by any means that are false, misleading or deceptive or likely to create an erroneous impression about the characteristics, health effects, hazards or emissions of any tobacco product or tobacco products, or about the health effects or hazards of tobacco use. Such a prohibition should cover, inter alia, use of the terms “low tar”, “light”, “ultra-light”, “mild”, “extra”, “ultra” and other terms in any language that may be misleading or create an erroneous impression.

86. A footnote to this passage states “[t]hese phrases are taken from Article 11.1(a) of the Convention, with the addition of the word “colour”, which the working

¹⁰⁷ Guidelines for Implementation of Article 11, para. 43.

group recognizes can be used to convey a misleading impression about the characteristics, health effects or hazards of tobacco products.”¹⁰⁸

3.4 State Practice

87. Consistent with Article 11 of the WHO FCTC, bans on misleading tobacco packaging are commonplace in the territory of WHO FCTC Parties and World Health Organization Member States. There is variation in the application of these bans from state to state. Nonetheless, state practice demonstrates two points.

88. First, Uruguay’s concern with respect to misleading packaging is shared by other states that are also implementing regulatory approaches, including those in the WHO FCTC and its Guidelines. For example, Australia has passed laws requiring ‘plain packaging’ of tobacco products, which requires retail packaging that permits only brand and variant names in a standardized font, style and size, against a standardized background. One of the express objects of the legislation is to “reduce the ability of the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products.”¹⁰⁹ Although Australia has prohibited the use of colours and other brand elements, whereas Uruguay has prohibited use of brand variants, Australia’s approach shows a similar concern regarding on-going consumer deception associated with branding. A number of other World Health Organization Member States are actively considering the introduction of plain packaging. Governments in France, Ireland New Zealand and the United Kingdom have backed the introduction of plain packaging in their jurisdictions.¹¹⁰

89. Second, although Uruguay’s law does not actually prohibit the sale of tobacco products (merely sale of tobacco products in a particular form), it is not uncommon for states to implement tobacco control measures that prohibit entire categories of tobacco products. For example, the 2014 EU Tobacco Products Directive prohibits the sale of tobacco products with a characterizing flavour other than tobacco, such as menthol-flavoured cigarettes.¹¹¹ This follows the introduction of similar laws in other countries, such as the United States, Canada and Brazil.¹¹² If similar

¹⁰⁸ Guidelines for Implementation of Article 13, para. 39, fn. 7.

¹⁰⁹ *Tobacco Plain Packaging Act 2011* (Cth), s3(2)(c) (currently the subject of an investment treaty claim and claims at the World Trade Organization).

¹¹⁰ With respect to France see [http://www.sante.gouv.fr/IMG/pdf/250914 - Dossier de Presse - PNRT 2 .pdf](http://www.sante.gouv.fr/IMG/pdf/250914_-_Dossier_de_Presse_-_PNRT_2_.pdf); With respect to Ireland see <http://www.oireachtas.ie/viewdoc.asp?fn=/documents/bills28/bills/2014/5414/document1.htm>. With respect to New Zealand see <http://www.legislation.govt.nz/bill/government/2013/0186/latest/DLM6220900.html>. With respect to Scotland see <http://scottishgovernment.presscentre.com/News/Tobacco-plain-packaging-3ce.aspx>. With respect to the United Kingdom see <https://www.gov.uk/government/news/government-backs-standardised-packaging-of-tobacco>

¹¹¹ Directive 2014/40/EU, Article 7.

¹¹² See respectively, *Family Smoking Prevention and Tobacco Control Act*, HR 1256, section 907(a)(1)(A); *Cracking Down on Tobacco Marketing Aimed at Youth Act*, an Act to amend the

restrictions were applied in Uruguay, the Marlboro 'Fresh Mint' variant would be prohibited not only because the term fresh implies healthfulness, but also on grounds that menthol flavour increases the palatability and attractiveness of tobacco products, particularly for children. This rationale is supported by a substantial body of scientific evidence¹¹³ and also by the WHO FCTC. In the latter respect, Partial Guidelines on implementation of Articles 9 and 10 of the Convention (regulation of the contents of tobacco products and of tobacco product disclosures) recommend that Parties "should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products."¹¹⁴

4. Conclusion

90. The action taken by Uruguay was taken in light of a substantial body of evidence that large graphic health warnings are an effective means of informing consumers of the risks associated with tobacco consumption and of discouraging tobacco consumption. There is also a substantial body of evidence that prohibiting brand variants is an effective means of preventing misleading branding of tobacco products. These bodies of evidence, which are consistent with state practice, support the conclusion that the Uruguayan measures in question are effective means of protecting public health.

Tobacco Act, 1997, sections 22 and 23; ANVISA (Brazilian Health Surveillance Agency) Resolution RDC 14/2012 (currently the subject of domestic litigation).

¹¹³ With respect to menthol specifically see Tobacco Products Scientific Advisory Committee (TPSAC) of the Center for Tobacco Products of the Food and Drug Administration (FDA), Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations (as reviewed at the TPSAC meeting on March 18, 2011).

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf>, p. 204 (in the PDF version).

¹¹⁴ 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/entity/fctc/guidelines/Guideliness_Articles_9_10_rev_240613.pdf?ua=1, para. 3.1.2.2.