UNITED STATES – MEASURES AFFECTING THE PRODUCTION AND SALE OF CLOVE CIGARETTES

(DS406)

Second Written Submission of the United States of America

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I. INTRODUCTION

1. Section 907(a)(1)(A) is a public health measure based on how cigarettes are used by the U.S. population as a whole. Cigarettes with certain characterizing flavors are prohibited under the measure because they are especially enticing to young people – and are therefore particularly harmful as they facilitate addiction – but also are not used by a large number of adults. As such, from a public health perspective, it is both desirable and appropriate to ban them. Indonesia's claims against section 907(a)(1)(A) rely on arguments that are either vague or wrong as a matter of law, and on factual assertions unsupported by evidence and refuted by the evidence submitted by the United States. And instead of engaging on the public health issues involving section 907(a)(1)(A) and youth smoking, Indonesia simply denies they exist.

2. Indonesia also ignores the fundamental concept that governments must often approach a pervasive, challenging public health problem – such as tobacco use – through incremental legislation. The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "FSPTCA") combats the overall problem of tobacco addiction through a variety of measures, many of which are of an incremental manner. Section 907(a)(1)(A) – one component of that law – is one among other incremental measures that are designed, collectively, to reduce tobacco use, especially among young people.

3. Indonesia likewise denies and attempts to belittle the concept that public health regulation must take account of possible negative consequences of proposed measures. The notion that banning menthol or tobacco cigarettes – the cigarettes smoked by most addicted smokers in the United States – would require additional research and study before implementation is openly derided by Indonesia. However, it is uncontroversial, from a public health perspective, that lesser-used harmful products can be removed from the market with fewer potential complications than more heavily-used products – especially when the product is addictive. Clove cigarettes and other cigarettes with characterizing flavors are entirely different from tobacco and menthol cigarettes from this regulatory perspective.

4. Indonesia also denies key facts about clove cigarettes. Despite the evidence, Indonesia rejects the fact that clove cigarettes were smoked disproportionately by young people in the United States. In an attempt to make clove cigarettes seem more like tobacco and menthol cigarettes and less like cigarettes with other characterizing flavors, Indonesia also denies or downplays basic attributes of clove cigarettes, such as that they are nearly equal parts clove and tobacco, and that consumers choose to smoke them because of their unique flavor and the aroma of the smoke.

5. These denials of fact are intended to sustain Indonesia's flawed legal arguments that section 907(a)(1)(A) violates the national treatment obligations under Articles 2.1 and 2.2 of the TBT Agreement and Article III:4 of the GATT 1994. With respect to national treatment, Indonesia maintains incorrectly that clove cigarettes are "like" tobacco and menthol cigarettes,

and that section 907(a)(1)(A) accords less favorable treatment to Indonesian products because it does not also ban every domestic cigarette. However, the relevant facts support that in the circumstances of this case, clove cigarettes are not "like" tobacco or menthol cigarettes. Moreover, the prohibition on flavors contained in section 907(a)(1)(A) in fact applies both to imported and domestic cigarettes, and does not apply to the vast majority of imported cigarettes.

6. Like its national treatment arguments, Indonesia's arguments with respect to Article 2.2 of the TBT Agreement fail. In particular, Indonesia has not adduced any, much less sufficient, evidence to establish that a reasonably available less trade restrictive measure exists that fulfills the objective of section 907(a)(1)(A) at the level the United States considers appropriate. As such, Indonesia has failed to establish a *prima facie* claim that section 907(a)(1)(A) is inconsistent with TBT Article 2.2.

7. If Members are to be able to begin to ban categories of cigarettes within their borders – as called for under the World Health Organization ("WHO") *Framework Convention on Tobacco Control* ("WHO Framework Convention")[1] – they must be able to identify and target, based on public health criteria, those cigarettes that they can effectively prohibit. Such a measure cannot be deemed more trade restrictive than necessary solely because it does not, standing alone, eliminate smoking entirely. In addition, such measures cannot be deemed to treat imported products less favorably than domestic products simply because one type of imported cigarette falls under the ban and one type of domestic cigarette does not fall under the ban, as suggested by Indonesia. To the contrary, in adopting the WTO Agreements, Members contemplated that measures that draw legitimate distinctions among products to protect the public health, such as the distinctions drawn by section 907(a)(1)(A), are not inconsistent with WTO obligations simply because they may have an effect on trade.

II. FACTUAL ISSUES

8. Indonesia incorrectly characterizes the facts in its submissions. As such, the United States will correct the record on a few important issues: (1) the concept of public health and its relevance to this dispute; (2) the appropriateness of incremental regulation; (3) the age group that smoking prevention measures seek to protect; (4) the public health concern of the cigarettes banned under section 907(a)(1)(A); (5) the import of the survey data; (6) the factual context leading up to the enactment of the Tobacco Control Act; and (7) the effect of section 907(a)(1)(A) on foreign and domestic products.

A. The Concept of Public Health Is A Key Aspect of This Dispute

[1] U.S. Answer to Q19, paras. 49-54. FCTC/COP/4/DIV/6, section 3.1.2.2, p. 53 (countries should "regulate, by *prohibiting* or restricting, ingredients that may be used to increase palatability in tobacco products.") (emphasis added).

9. Indonesia repeatedly claims that clove cigarettes are not more toxic than other cigarettes not banned under section 907(a)(1)(A).[2] As discussed in prior U.S. submissions, the issue of toxicity is of only limited relevance for Indonesia's legal claims.[3] And as this section will explain, Indonesia's reliance on toxicity reflects a fundamental misunderstanding of the public health goals of the challenged measure.

10. The distinct health risk posed by "trainer" cigarettes, such as candy, fruit, clove, and the other cigarettes banned under section 907(a)(1)(A), does not derive from the effect of these cigarettes on an individual user. Rather, the health risk derives from the public health perspective of how these products are used.[4] These products are used disproportionately by young people, and not in large numbers by adults. The banned cigarettes contain characterizing flavors that entice young people to try them, resulting in them becoming addicted smokers.[5] Accordingly, as discussed below, from a public health perspective, it is both desirable and appropriate to eliminate these products from the market.

11. The evidence on the record in this dispute shows that clove and other flavors are especially attractive to young people in the age window of initiation, and therefore tend to contribute to addiction. As detailed in the Tobacco Control Act, a number of factors supported a product standard that resulted in a ban on clove and other flavors, but that did not result in a ban on all cigarettes.[6] Those factors include:

- "the risks and benefits to the population as a whole";[7]
- "the increased or decreased likelihood that those who do not use tobacco products will start using tobacco products";[8] and
- "the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the

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[2] *See, e.g.*, Indonesia First Written Submission, para. 90-91; Indonesia Answer to Q36, para. 82.

[3] *See* U.S. Answer to Q18, paras. 46-48; U.S. Answer to Q40, paras. 98-101.

[4] *See, e.g.*, WHO, The Scientific Basis of Tobacco Product Regulation," WHO Technical Report Series 945, at 27 (2007) ("WHO, The Scientific Basis of Tobacco Product Regulation") ("The harm caused by tobacco products is a function of their toxic emissions *as well as the extent and their patterns of use*. Patterns of use, in turn, are related to dependence potential and consumer appeal.") (emphasis added), Exhibit US-113.

[5] *See* U.S. Opening Statement, para. 3 (noting that of those people that have ever tried smoking, about one-third become daily smokers).

[6] Sec. 907(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by the FSPTCA, Exhibit US-7.

[7] Sec. 907(a)(3)(B)(i)(I) of the FFDCA, as amended by the FSPTCA, Exhibit US-7.

[8] Sec. 907(a)(3)(B)(i)(II) of the FFDCA, as amended by the FSPTCA, Exhibit US-7.

> creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand."[9]

12. As reflected in the Tobacco Control Act, it may not be appropriate for the public health simply to entirely ban a harmful class of products, such as all cigarettes. Public health policy is not simply a matter of enshrining into law ideal scenarios and outcomes. If it were, laws would require drugs to have no side effects, regardless of their benefits, and new cars to have every available safety feature, regardless of how many people would continue to drive their existing, and less-safe, cars due to the high cost of buying a new car. Public health policy involves a balancing of a complex set of factors, including the relative harms of certain products, how those products are used by consumers, and the possible shortcomings or countervailing factors of proposed measures. Ultimately, public health policy is guided both by what is desirable and by what is appropriate, taking into account the multiple relevant public health considerations, which often do not point to the same result.

13. The Tobacco Control Act establishes that tobacco product standards, including section 907(a)(1)(A), should be adopted when they are appropriate to protect the public health - including whether they are technically achievable, feasible, and effective. The WHO Tobacco Convention captures this principle as well by stating that countries should "aim to implement the most effective measures that they can achieve."[10]

14. The Tobacco Control Act takes into account both what is optimal or desirable with respect to the health of individuals and what is appropriate with respect to the population as whole. It may be desirable to remove all cigarettes from the market, as all cigarettes are harmful to individual smokers. However, for the reasons the United States has explained, it is not currently appropriate to do so.

B. Incremental Regulation Is a Normal and Sound Manner of Regulating Smoking

15. Indonesia argues repeatedly that the United States has acted inconsistently with its obligations by prohibiting some, but not all, cigarette products. Specifically, Indonesia contends that the United States may not eliminate clove cigarettes from the market without also taking the same action against tobacco and menthol flavored cigarettes,[11] which, for all practical purposes, means all U.S. cigarettes. This argument is a key contention for Indonesia, and it relies heavily on

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[9] Sec. 907(b)(2) of the FFDCA, as amended by the FSPTCA, Exhibit US-7.

[10] FCTC/COP/4/DIV/6, sec. 3.1.2, p. 52, Exhibit US-67.

[11] *See, e.g.*, Indonesia Opening and Closing Statement, para. 23 ("The ban on flavored cigarettes by the United States is discriminatory and was not "necessary" to address concerns with youth smoking. Therefore, the ban on some characterizing flavors in cigarettes, but not menthol and tobacco, is an unnecessary obstacle to international trade."); Indonesia First Written Submission, section V.A.1c (discussing Indonesia's like product argument); Indonesia Answer to Q12(b), para. 39 (discussing Indonesia's TBT Article 2.2 argument).

this contention throughout its national treatment and TBT Article 2.2 claims. As discussed below, however, Indonesia's position ignores that: (i) Members often regulate incrementally; (ii) Members make regulatory distinctions between products that have differing effects on public health; and (iii) Members often use more than one type of regulatory tool to address a public health problem. Indonesia's position further ignores that the United States has taken this approach with smoking for the past half century (reducing smoking prevalence as a result), as well as the fact that the United States has a sound public health basis for not prohibiting all of the different types of cigarettes.

16. It simply cannot be that the WTO Agreement prevents Members from addressing part of a problem in a step by step manner, making distinctions among products based on sound public health considerations. Indonesia ignores this obvious truth and attempts to use the international trade rules to hold the United States hostage to the fact that tens of millions of adults are addicted to smoking tobacco and menthol flavored cigarettes.

1. The United States Often Addresses Difficult Issues Incrementally

17. The United States does not represent that either the challenged measure or the Tobacco Control Act as a whole will eliminate the problem of smoking. Rather, all of the Act's provisions, including section 907(a)(1)(A), work to reduce the problem of smoking and tobacco use. Section 907(a)(1)(A) specifically addresses the problem of certain products with characterizing flavors of candy, fruit, clove, etc., that are used by young people disproportionately and whose precipitous withdrawal from the market can be done effectively without the potential for negative consequences. This provision, along with the other provisions of the Act, build upon the many other measures during the past half century.

18. Contrary to Indonesia's argument, the United States has taken an incremental approach to the complex problem of smoking for the last fifty years. For example, the very first nation-wide law related to tobacco prohibited advertising by the cigarette companies, but only prohibited advertising on television and radio. Since the television and radio ban in 1971, restrictions on advertising were expanded by the Master Settlement Agreement ("MSA") in 1998, which restricted advertising on billboards and the use of cartoon images. The Tobacco Control Act adds further restrictions, such as prohibiting tobacco brand name sponsorship of any athletic, musical, or other social or cultural events,[12] and gives FDA authority to enact additional regulatory controls, such as additional restrictions on the sale, distribution, advertising, and promotion of tobacco products that are appropriate for the protection of the public health.[13] Federal restrictions on where a smoker can use the product started with a ban on smoking on some domestic airline flights in 1988 and all flights to and from the United States by 2000.

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[12] *See* Tobacco Control Act, sec. 102(a) (directing FDA to issue a regulation that has been codified at 21 C.F.R. sec. 1140.34(c).

[13] *See* sec. 906(d) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

19. The incremental effect to addressing the public health effects of smoking may also be seen in U.S. state and local laws. Over the last 10 years, state and sub-state measures protecting individuals from secondhand smoke in workplaces and public places have become more common throughout the country. Currently, 25 states, Puerto Rico, the District of Columbia, and over 400 other communities have smoke-free laws that are considered comprehensive (*i.e.*, laws that prohibit smoking in all indoor areas of workplaces, restaurants and bars). Several of these states and communities that have achieved comprehensive status did so incrementally, either by first prohibiting smoking in certain workplaces or public places or by enacting less restrictive (and less effective) measures such as requiring smoking take place in designated indoor smoking areas. It is also common that these state measures gain momentum and lead to federal legislation. In that regard, efforts taken by the states with respect to cigarettes with characterizing flavors, such as the 2006 Consent Agreement, could be seen as setting the stage for regulation at the national level.[14]

20. Such an approach is neither unusual nor surprising. The United States notes that other countries have regulated particular smoking-related issues in such a manner,[15] and the United States has regulated other difficult issues through the same incremental approach, including the restricting of ozone depleting products.[16] The WHO's Tobacco Convention is consistent with an incremental approach. The WHO Tobacco Convention does not attempt to impose rules that will eliminate smoking entirely, but to set rules that will assist countries in reducing the smoking rates of their domestic populations.[17]

2. The United States Has a Sound Public Health Basis for Regulating Incrementally in Addressing the Issue of Characterizing Flavors

21. As we have previously discussed, the United States has not banned all cigarettes because the prohibition of the heavily-used tobacco and menthol flavored products may cause negative consequences.[18] Indonesia not only disregards – but attempts to belittle – the public health consequences for the individual addict, the U.S. health care system, and the society at large through an expansion of an already existing black market that would result from banning all of the

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[14] *See* HR Rep't, at 37 (referring to the 2006 Consent Agreement), Exhibit US-67.

[15] *See, e.g.*, Bryan-Jones & Chapman, "Political dynamics promoting the incremental regulation of secondhand smoke: a case study of New South Wales, Australia," BMC Public Health, 2006, 6:192 (July 21, 2006), Exhibit US-114.

[16] Ozone-depleting substances ("ODSs") are harmful to the environment because they decrease the protective ozone layer above the Earth. The United States, along with most other countries, is eliminating them pursuant to the Montreal Protocol on Substances that Deplete the Ozone Layer. While they are largely banned, they can be used in essential medical products if so approved.

[17] *See* U.S. Answer to Q19, paras. 53-54.

[18] *See* U.S. First Written Submission, paras. 232-238; U.S. Opening Statement, para. 12.

different types of cigarettes.[19] Indonesia's stance is unsupportable – it is *self-evident* that the elimination from the market an entire class of products that is as addictive as heroin or cocaine,[20] and to which tens of millions of people are in fact addicted, would have, at the very least, *some* consequences.[21]

22. Cigarettes are a unique class of products – they are highly addictive, heavily used, harmful to public health, and legal. The combination of these factor creates complex problems for governments charged with protecting the public of their citizens. This is not to say that some regulatory measures cannot apply across-the-board to all of the different types of cigarettes. For example, the United States requires health warnings on all packages of cigarettes and smokeless tobacco products. Other types of measures, however, call for a more tailored approach.

23. In addition to the epidemiologic concerns, Members may legitimately elect to concentrate on those products that, even though they have a limited segment of the market, present distinct public health concerns from other products, and available information indicates that such action will not have significant negative public health consequences. Other, perhaps more commonly used, products might be set aside temporarily for further study with regard to the consequences of particular proposals. This is precisely what the United States has done, by banning most characterizing flavors, but assigning menthol-flavored cigarettes to intensive study by the Tobacco Products Scientific Advisory Committee ("TPSAC") to better understand the public health issues related to possible future restrictions.[22]

24. Different jurisdictions will examine these same regulatory issues, and adopt what are sometimes very different approaches. For example, Bhutan (as discussed below) attempted to

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[19] *See* Indonesia Opening and Closing Statement, para. 79 (The U.S. "claims [] are nothing short of ridiculous."); *id.* para. 80-81 ("They're just making it up. . . . And then there's my favorite "reason" for not banning menthol cigarettes. Listen to this. If you ban menthol cigarettes, it could lead to a black market in them that would, and now I'm quoting, "increase youth access." If you believe that, then why did the U.S. ban clove cigarettes? I thought the whole idea was to restrict youth access? The bottom line here is that they're making this stuff up as they go along. It's all, or mostly, post-hoc rationalizations intended to justify a measure that has no justification."). We would further note that Indonesia has apparently leveled its unfounded by convenient accusation that the entire U.S. line of reasoning is a recent invention of the lawyers is incorrect. *See* Indonesia Opening and Closing Statement, para. 81. Both FDA in 1996 and Congress in 2009 noted that banning other cigarettes not banned under section 907(a)(1)(A) may cause to negative consequences. *See* U.S. First Written Submission, para. 22 (quoting from FDA's 1996 rule); para. 236 (quoting from the HR Rep't, at 38, Exhibit US-67).

[20] U.S. Centers for Disease Control and Prevention ("CDC"), Cessation web page, Exhibit US-115.

[21] Indonesia is thus wrong to contend that the key statistic is whether menthol cigarettes are widely used by people under the age of 18. *See, e.g.*, Indonesia Opening and Closing Statement, para. 84. The reason menthol cigarettes (and tobacco-flavored cigarettes) are not banned is not because adolescents do not use them, rather it is because they are so heavily used by the adult population. With regard to menthols, the key point, therefore, is not a figure at all, and certainly not the prevalence rate among adolescents, but rather that there are many adult menthol smokers, measuring in the tens of millions (currently estimated at 17 million).

[22] U.S. First Written Submission, paras. 136-139.

address the public health consequences of smoking by banning all of the different types of cigarettes. (No other jurisdiction has attempted this approach.).

25. The complainant in this dispute seems to lie at the other extreme of the spectrum in terms of regulating tobacco use. Indonesia is the third biggest tobacco consumer in the world, with more than 60 million citizens smoking 240 billion cigarettes in 2008. Indonesia has close to 20 million more smokers than the United States, despite having close to 75 million fewer people.[23] Apparently as a result of the large level of domestic usage, cigarette companies are among the largest employers and taxpayers in Indonesia.[24]

26. Indonesian senior government officials as well as top Indonesian scientists have made headlines recently by contending that:

- cigarettes are not addictive;[25]
- restrictions on smoking should be viewed with caution as cigarettes are *halal*, the sale of which generates significant tax revenue;[26] and
- smoking may be good for you, and even if it causes negative health effects, those effects are mild and can be easily countered with lowering one's stress level (by smoking).[27]

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[23] Pasandaran & Sagita, "Some Indonesian Experts Say That Smoking Could Be Good for You," Jakarta Globe (December 14, 2010) (citing WHO statistics) ("Some Indonesian Experts Say That Smoking Could Be Good for You"), Exhibit US-116. Indonesia estimates the population of Indonesia at 234.2 million people, http://dds.bps.go.id/eng/aboutus.php?sp=1, while the United States estimates the U.S. population at 308.7 million. http://www.census.gov/.

[24] *See* Kurniawati & Rachman, "Big Tobacco's Big Influence Keeps Indonesia Lighting Up," Jakarta Globe (November 1, 2010), Exhibit US-117.

[25] Camelia Pasandaran, "Indonesian Government Witnesses Say Tobacco Not Addictive," Jakarta Globe (January 5, 2011) ("Indonesian Government Witnesses Say Tobacco Not Addictive") (Mualimin Abdi, the Director of litigation at the Justice and Human Rights Ministry, testified before the Constitutional Court that tobacco is not addictive: "It's nonsense to say that it's difficult to quit smoking. ... It didn't take me weeks to stop smoking. I just stopped. It only takes strong willpower."), Exhibit US-118.

[26] *Indonesian Government Witnesses Say Tobacco Not Addictive* (According to an Indonesian legislator, "[t]obacco is a halal product [accepted under Islam], therefore cigarettes are halal too. ... People should also not close their eyes to the fact that we receive Rp 60 trillion [$6.6 billion] in tobacco excise every year."), Exhibit US-118.

[27] *See Some Indonesian Experts Say That Smoking Could Be Good for You*, Exhibit US-116; *see also id.* (Aris Widodo, a professor of pharmacology in Indonesia, testified before the Indonesian Constitutional Court that "'[t]hough incidents of disease related to smoking are relatively high, it should be understood that smoking is not the only factor, as genetic factors and pollutants play a role too.' Stress, he added, was another important factor. 'But that could be solved easily by smoking cigarettes instead of using other drugs.'").

27. These statements reflect Indonesia's societal views on smoking. These extreme views, however, are outside the mainstream of international public health policy and should not be imposed on other WTO Members.

28. Returning to the specifics of the incremental approach that the United States is pursuing through the adoption of section 907(a)(1)(A), Indonesia apparently disagrees with the U.S. view that precipitously banning heavily used, highly addictive products could result in a significant stress for the U.S. health care system to absorb.[28] Instead, Indonesia contends that any stress would be insignificant in that the increase in ambulatory care visits would only be 0.25%.[29]

29. Indonesia makes two rudimentary errors in this regard. First, Indonesia includes specialty care visits when doing their calculation; in reality, it is highly unlikely that those interested in quitting would consult with an endocrinologist, oncologist, rheumatologist, or any other specialist. Second, Indonesia assumes that the smoking cessation visits would occur over the course of a year. In reality, if any increase in visits to primary care providers around cessation were to occur, it is reasonable to assume that they would occur shortly after a ban occurred and almost certainly in the first month. As a result, Indonesia underestimates what the potential impact on the health care system might be.

30. With regard to the expansion of the black market, the United States has already presented evidence establishing the existence of a multi-billion dollar black market for cigarettes in the United States at this time, and the consequences of a possible expansion of such a market were the United States to ban menthols.[30]

31. Indonesia also criticizes the United States for considering the potential consequences of banning menthol cigarettes to be a serious question.[31] Again, such a position seems odd to the United States. As we have stated, the United States has very little experience in banning a product as heavily used and as addictive as menthols, and has no U.S.-specific data to draw

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[28] *See* U.S. First Written Submission, para. 23.

[29] *See* Indonesia Opening and Closing Statement, para. 80.

[30] *See* U.S. First Written Submission, paras. 24-26 (citing to a U.S. Treasury Department report, Exhibit US-27, estimating that approximately $2 billion dollars in federal excise tax revenue is lost each year to the black market).

[31] *See* Indonesia Opening and Closing Statement, para. 83 ("Indeed, ... the U.S. concedes that they don't know any of this to really be true. If you look at ¶ 226, when talking about Indonesia's claims under Art. 2.2 of the TBT Agreement, they state …"such negative consequences may include the unknown, but possibly negative, impact on the health of adult smokers and the U.S. health care system generally, as well as an expansion of the already existing black market for cigarettes in the United States.") (emphasis in original).

from.[32] Moreover, as far as the United States is aware, no country has imposed a comprehensive ban on all, or a large portion, of cigarettes in the country with one exception – Bhutan.[33]

32. Given the paucity of data sources – none of them U.S. specific – that the United States can draw from, it is not surprising that there exists serious question as to what would happen if the United States prohibited the production and sale of menthol cigarettes.[34] However, Indonesia's argument, that the United States can not prohibit clove cigarettes – *regardless of that product's public health risk* – until the United States bans *all* cigarettes, is unreasonable and not supportable by any provision in the WTO Agreement that it cites. The United States knows of no reason why it must be held hostage to such an extreme standard when regulating for the public health, and Indonesia has put forth no such a reason.

C. The Window of Smoking Initiation

33. At the Panel's first substantive meeting, and again in answers to the Panel's questions, the United States established that the window of initiation for smoking to be approximately between the ages of 12 and 26.[35] Indonesia does not directly respond to this point, only stating that "the break point for adulthood is 18."[36] Indonesia's argument misses the point. The line between youth and adulthood will be drawn differently, depending on the goal of the particular demarcation. In the United States, persons must be 18 in order to vote. But other ages are used for different purposes; for example, persons must generally be 15 or 16 in order to drive, and must be 21 in order to drink alcoholic beverages. And the voting age has nothing to do with the public health issues involved with tobacco addiction.

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[32] U.S. Answer to Q63, para. 144.

[33] In 2004, Bhutan enacted a national sales ban on cigarettes. *See* Givel, *Tobacco Use Policymaking and Administration in Bhutan* (November 2009), Exhibit US-109. Individual consumption of tobacco was allowed along with a 100% sales tax and 100% import tax if the tobacco was imported into Bhutan for personal use. Tobacco imported from India was subject only to the 100% sales tax due to a free trade agreement with Bhutan. The consequences of the law included a robust black market, significant tobacco smuggling, continued smoking in entertainment venues, and continued smoking by some segments of the population, particularly young people, and the measure was withdrawn a few years later. It appears in 2010 that Bhutan imposed another strict restriction on the internal sale of cigarettes, although it is too early to tell what the consequences of this law will bring.

[34] *See* U.S. Answer to Q63, para. 144-147. As the United States has noted previously, this is one of the issues that is before the TPSAC, a Committee the U.S. Congress directed to investigate the "the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities." Section 907(e)(1) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

[35] *See* U.S. Answer to Q12(b), para. 16. As is clear from this answer, the United States does not agree with Indonesia that the United States has used "youth" to mean only people under age 18, but has rather used the term "youth" and "young people" interchangeably to refer to people within the age of initiation. *Compare* Indonesia Answer to Q12(b), para. 38. As noted, the United States will use the term "young people" going forward.

[36] Indonesia Answer to Q12(b), para. 38.

34. Rather, the issue is rather in what age group do the vast majority of people try their first cigarette as well as transition from the occasional smoker to a regular smoker. That is the age group upon which public health authorities sensibly focus their attention on for many tobacco regulatory initiatives, and it is that age group that section 907(a)(1)(A) protects from the dangers presented by cigarettes with characterizing flavors of candy, fruit, clove, etc. by its focus on reducing initiation.

35. As noted at the Panel's first substantive meeting, the fact that all "young people" (*i.e.*, "children" and "young adults") are at risk for smoking initiation and becoming daily smokers is well-established from high-quality nationally representative survey data. For example, the 2008 National Survey of Drug Use and Health ("NSDUH") found that among current or former daily smokers, 98.4% of them had tried a cigarette before age 26, and 95.3% had become daily smokers by then.[37] In contrast, among current or former daily smokers, 86.6% had tried a cigarette before age 18 and 64.1% had become daily smokers by then.[38] In terms of absolute numbers, this means that 704,000 people under the age of 18 began smoking daily in 2009 and 343,000 individuals age 18-26 began smoking daily in 2009.[39]

36. Under section 907(a)(3) of the FFDCA, as amended by the Tobacco Control Act, FDA may adopt a tobacco product standard, including one that reduces or eliminates an additive or constituent, if the standard is appropriate for the protection of the public health. Whether a standard is appropriate for the protection of the public health is based on several considerations, including "the increased or decreased likelihood that those who do not use tobacco products will start using such products." In other words, the focus is on reducing initiation among the

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[37] Exhibit US-89.

[38] Exhibit US-89. The United States would also note that these numbers have changed very little over last few decades, and data from the 1991 National Household Survey on Drug Abuse (now known as NSDUH) provide similar figures. 1994 U.S. Surgeon General Report, at 49 table 7, Exhibit US-119.

[39] The United States notes that based on the same data some experts conclude that the age of initiation ends at age 24 or 25. Regardless of the exact end point, it is well-established in the scientific community that a sizable portion of adults that are regular smokers became regular smokers during their late teens or early twenties. *See, e.g.*, Wechsler, *et al*, "Increased Levels of Cigarette Use Among College Students: A Cause for National Concern," Journal of American Medical Association (JAMA), vol. 280, no. 19, at 1677 (November 18, 1998) ("Increased Levels of Cigarette Use Among College Students") ("more than one quarter (28%) of current smokers began to smoke regularly at age 19 or older"), Exhibit US-92; Ling & Glantz, "Why and How the Tobacco Industry Sells Cigarettes to Young Adults: Evidence from the Industry Documents," American Journal of Public Health, Vol. 92, No. 6, at 908 (June 2002) ("Why and How the Tobacco Industry Sells Cigarettes to Young Adults") ("The number of 18- to 19-year-olds in the early stages of smoking initiation is more than twice the number of 18-year-old established smokers. These youths are at risk to become established smokers as young adults and thus are prime targets for interventions to make them nonsmokers again."), Exhibit US-93; Lantz, "Smoking on the rise among young adults: implications for research and policy," Tobacco Control 2003 12, at i66 ("In summary, the epidemiology of cigarette smoking indicates that smoking initiation primarily occurs in adolescence, the majority of smokers are still trying their first cigarette in early adolescence, and making the transition to habitual smoking by age 19. However, it is also the case that a significant proportion of smokers establish regular or habitual smoking as young adults. Analyses on FHIS survey data suggest that this proportion has been sizeable for some time, and that it increased, particularly among males, during the late 1990s."), Exhibit US-94.

population generally, such that the window of initiation is a key concept, and is by no means limited to the risk to children. The Tobacco Control Act takes a similar approach with respect to other regulatory measures that consider the effects on initiation among the population generally, such as restrictions on the sale and distribution of tobacco products,[40] FDA's review of new tobacco product applications,[41] and FDA's review of modified risk tobacco product applications.[42] In addition, section 907(a)(3), similar to other provisions of the law, directs FDA to take into account the risks to the population as a whole of a possible tobacco product standard. This includes the impact on both users and nonusers of tobacco product, and not just users under the age of 18.

37. Consistent with this approach, smoking prevention programs in the United States target all people within this window of initiation. Many of these programs target adolescents,[43] while other programs target young adults, particularly those that are university students.[44] These programs are in line with scholarship on this subject in the previous years, which argue that smoking prevention should target not just people under the age of 18, but young adults in their later teens and early twenties as well.[45]

38. Further undermining Indonesia's position is the fact that cigarette companies themselves have long targeted young people generally, both adolescents and young adults, and based on recent scholarship, continue to do so.[46] Young adults in particular are a key demographic, not

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[40] Sec. 906(d)(1) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

[41] Sec. 910(c)(4) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

[42] Sec. 911(g)(4) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

[43] There are numerous programs in the United States targeting smoking initiation among adolescents. The following websites describe but a fraction of them: http://www.cdc.gov/HealthyYouth/tobacco/guidelines/index.htm; http://www.nsba.org/MainMenu/SchoolHealth/TobaccoConsortium.aspx; http://www.cdc.gov/tobacco/stateandcommunity/bp_userguide_youth/index.htm.

[44] The Tobacco Technical Assistance Consortium has numerous pages devoted to tobacco prevention among university age students. *See* http://ttac.org/services/college/index.html. Other examples of such programs include Tobacco Free U., http://www.tobaccofreeu.org/, a state of Montana program http://tobaccofree.mt.gov/MontanaCollegiateTobaccoPreventionInitiative.shtml, and a California program targeting both adolescents and young adults. http://www.cyanonline.org/. Many other programs exist.

[45] *See, e.g.*, *Why and How the Tobacco Industry Sells Cigarettes to Young Adults*, at 914 (noting as well that stopping smoking before age 30 eliminates virtually all of the long-term mortality effects), Exhibit US-93*; Increased Levels of Cigarette Use Among College Students*, at 1677-78, Exhibit US-92; *see also id.* at 1673 ("Data suggest that college is a time of considerable change in smoking behavior. The college years provide a window of opportunity for interventions focused on blocking the transition from occasional smoking to regular nicotine-dependent smoking and for efforts to increase success.").

[46] *See, e.g.*, Hendlin, *et al*, "'Acceptable rebellion': marketing hipster aesthetics to sell Camel cigarettes in the US," Tobacco Control, 2010 19: 213-222 ("Acceptable Rebellion"), Exhibit US-96; Biener & Albers, "Young Adults: Vulnerable New Targets of Tobacco Marketing," American Journal of Public Health, Vol. 94, No. 2, at 326-330 (February 2004) ("Young Adults: Vulnerable New Targets of Tobacco Marketing"), Exhibit US-97; *Why and How the Tobacco Industry Sells Cigarettes to Young Adults*, at 908, Exhibit US-93, stating:

only because they are within the age of the initiation and can be legally targeted by the cigarette companies, but because they are trend setters for potential adolescent customers.[47] Moreover, the cigarette companies are well aware that:

> cigarette brands enjoy the highest brand loyalty of all consumer products, with less than 10% changing brands annually. Brand choices are usually made early during the life of a smoker, with a high concordance between the brand first smoked and the brand eventually selected as a usual brand. Thus, once a consumer embraces a cigarette brand, it is quite unlikely that they will change.[48]

39. According to a previously secret, internal RJ Reynolds strategic research report entitled "Younger Adult Smokers: Strategies and Opportunities":

> In every sense, companies with strong younger adult brands hold the *high ground*, standing above the increasingly difficult and costly battle for switchers.[49]
>
> ...
>
> Younger adult smokers are the only source of replacement smokers, repeated government studies have shown that: less than one third of smokers (31%) start after age 18. Only 5% of smokers start after age 24. Thus, today's younger adult smoking behavior will largely determine the trend of Industry volume over the next

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> First, the industry views the transition from smoking the first cigarette to becoming a confirmed pack-a-day smoker as a series of stages that may extend to age 25, and it has developed marketing strategies not only to encourage initial experimentation (often as teens), but also to carry new smokers through each stage of this process. Second, industry marketers encourage solidification of smoking habits and increases in cigarette consumption by focusing on key transition moments when young adults adopt new behaviors such as entering new workplaces, school, military, and especially leisure and social activities. Third, tobacco companies study young adults' attitudes, social groups, values, aspirations, role models, and activities, and infiltrate both their physical and social environments.

[47] *Acceptable Rebellion*, at 213 ("Since the [MSA] severely restricted under-18 directed tobacco advertising, the major tobacco companies have increasingly targeted young adults who represent an important market for tobacco companies and also set trends for adolescents. The small segment of the population who serve as 'innovators' and 'early adopters' of new trends influence consumer trends for the rest of society."), Exhibit US-96.

[48] Wakefield, *et al.*, "The cigarette pack as image: new evidence from tobacco industry documents," Tobacco Control 2002; 11 (Supp I), at i73, Exhibit US-120

[49] RJ Reynolds, Secret Strategic Research Report, "Younger Adult Smokers: Strategies and Opportunities," at 2 (February 29, 1984) ("RJ Reynolds, Younger Adult Smokers: Strategies and Opportunities") (emphasis added), Exhibit US-121.

> several decades. *If younger adults turn away from smoking, the Industry must decline, just as a population which does not give birth will eventually dwindle.*[50]

40. In another previously secret internal RJ Reynolds memorandum, the company explains that "younger adult smokers will be considered as a *primary target* for *new brand product* benefits that demonstrate younger adult as well as broader smoker appeal."[51] As explained in this same memorandum, one of the new types of product that RJ Reynolds was in the process of developing was cigarettes with new characterizing flavors.[52]

D. The Cigarettes Banned Under Section 907(a)(1)(A), Including Clove Cigarettes, Raise Serious Public Health Concerns

1. Cigarettes With Characterizing Flavors That Are Banned Under Section 907(a)(1)(A) Raise Serious Public Health Concerns

41. Internal cigarette company documents indicate that there is a strong correlation between product design and market share of young smokers.[53] Overall, the cigarette companies recognize that in order to attract new smokers, they need to design a seemingly milder product than regular smokers may choose to consume.[54] One of the key design innovations of the 1990's was to introduce new characterizing flavors to the market, which adds a "sweet taste," and different, tingling feeling, that is not as rough.[55] Such flavors would create a novel and heightened sensory experience.[56] It is well-established that the cigarette companies designed many of the banned cigarettes specifically to attract young people to these products.[57]

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[50] RJ Reynolds, *Younger Adult Smokers: Strategies and Opportunities*, section 1, at 2 (emphasis added), Exhibit US-121.

[51] RJ Reynolds, "New Brands: Opportunities and Supporting Technologies," at 8 (1986), Exhibit US-122.

[52] RJ Reynolds, "New Brands: Opportunities and Supporting Technologies," at 10-11, Exhibit US-122.

[53] Wayne & Connolly, "How cigarette design can affect youth initiation into smoking: Camel cigarettes 1983-93," Tobacco Control 2002; 11, at i37 (Suppl I) ("How Cigarette Design Can Affect Youth Initiation Into Smoking"), Exhibit US-95.

[54] *How Cigarette Design Can Affect Youth Initiation Into Smoking*, at i34, Exhibit US-95.

[55] *How Cigarette Design Can Affect Youth Initiation Into Smoking*, at i35, Exhibit US-95.

[56] Manning, *et al.*, "Flavoured cigarettes, sensation seeking and adolescents' perceptions of cigarette brands," Tobacco Control, 18: 459-465, at 459 (2009) ("Flavoured Cigarettes, Sensation Seeking and Adolescents' Perceptions of Cigarette Brands"), Exhibit US-123.

[57] U.S. Answer to Q12(c), para. 19 (citing Lewis & Wackowski, "Dealing with an Innovative Industry: A Look at Flavored Cigarettes Promoted by Mainstream Brands," American Journal of Public Health, Vol. 96, No. 2, at 1601-1608 (February 2006) ("A Look at Flavored Cigarettes Promoted by Mainstream Brands"), Exhibit US-33; Wayne & Connolly, "How cigarette design can affect youth initiation into smoking: Camel cigarettes 1983-93," Tobacco Control 2002; 11 (Suppl I), at i35 ("How Cigarette Design Can Affect Youth Initiation"), Exhibit US-95).

42. As discussed previously, the U.S. cigarette companies spent decades developing these new products.[58] In 1995, RJ Reynolds appears to have been considering a number of different flavors, including flavors of candy, liquor, and, not surprisingly, clove.[59] RJ Reynolds launched its Camel Exotic Blends line in 1999 with three flavored sub-brands, and by 2005 had introduced 16 additional flavored sub-brands, including cigarettes with candy, liquor, and spice characterizing flavors.[60] RJ Reynolds aggressively marketed the Exotic Blends line on a wide variety of fronts, including in normal retail outlets, magazines, as well as through direct mail promotions, websites, and bars.[61]

43. It is clear that these flavored cigarettes had a disproportionate appeal among young, novice smokers.[62] In fact, even Indonesia concedes that the research supports the fact that children "think flavored tobacco products are safer and less addictive than regular tobacco products."[63] Such products therefore represented a serious public health concern that warranted regulation. The weight of the scholarship on this subject is clear.[64]

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[58] *See* U.S. First Written Submission, paras. 43-53.

[59] RJ Reynolds Letter to the New England Consulting Group (June 20, 1995), Exhibit US-124, listing "new brand ideas," which included ideas for flavored products:

> 2. Sage (herbal cigarette accented with sage and other herbs); 4. Aura (floral aroma/specially scented for women); 6. Sierra (woodsy aroma of pine); 8. Long Green (eucalyptus and pine in a menthol); 14. Napoleons (cured with brandy); 16. Perk (coffee); 22. Cherry Tree (cherry); 126. Lemon (menthol flavored with lemon); 138. Flavored filter cigarette concept – new brand of filter cigarette with choice of flavors – spearmint, cherry ming, or peppermint; 158. Wine Flavored (burgundy); 159. Wine Flavor #2 (sherry wine), #3 apple wine, #4 champaign; 178. Lipstick (apple aroma cigarette for women); 179. Malt (new flavor that is a blend of tastes); 188. Clove (clove flavored cigarette); 189. Liquor/candy flavored cigarette: brandy, cognac, chocolate, chocolate mint; and 194. Fresh Breath (cigarette that provides fresh breath)).

[60] *See* U.S. First Written Submission, para. 48.

[61] *A Look at Flavored Cigarettes Promoted by Mainstream Brands*, at 246, Exhibit US-33; Sepe, *et al.*, "Smooth Moves: Bar and Nightclub Tobacco Promotions That Target Young Adults," American Journal of Public Health, Vol. 92, No. 3, at 414-419 (March 2002) ("Bar and Nightclub Tobacco Promotions That Target Young Adults"), Exhibit US-101; *see also* U.S. Answer to Q12(c), para. 21 (citing *New Cigarette Brands with Flavors that Appeal to Youth*, at 1601-1608, Exhibit US-40; *Why and How the Tobacco Industry Sells Cigarettes to Young Adults*, at 908-916, Exhibit US-93; *Acceptable Rebellion*, at 213-222, Exhibit US-96; *Young Adults: Vulnerable New Targets of Tobacco Marketing*, at 326-330, Exhibit US-97).

[62] Exhibit US-53, at 7; U.S. First Written Submission, section III.F; *see also* WHO, *The Scientific Basis of Tobacco Product Regulation*, at 27 ("[I]nternal industry research suggests that young and inexperienced smokers may also be especially vulnerable to product benefits related to flavoured cigarettes."), Exhibit US-113.

[63] Indonesia Answer to Q37, para, 83.

[64] *See, e.g.*, *Flavoured Cigarettes, Sensation Seeking and Adolescents' Perceptions of Cigarette Brands*, at 464 ("Despite the legislative progress that has been made to date, the use of flavour descriptors by cigarette companies . . . will probably remain a public health concern and in the policy spotlight for years to come."), Exhibit US-123; Carrie M. Carpenter, *et al.*, "New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies," Health Affairs, Vol. 24, No. 6, at 1608 (Nov./Dec. 2005) ("New Cigarette Brands with Flavors that

44. Indonesia, however, claims these new products are not do not pose such a concern as they are not "gateway" products.[65] For this proposition, Indonesia relies on the writings of a *single* individual, Dr. Michael Siegel, which have been disseminated on his personal website.[66]

45. Not only do Dr. Siegel's opinions run counter to the clear opinion of academics in the field, all of whom have published their views in peer reviewed journals, but also to the WHO's conclusions in its own report entitled "The Scientific Basis of Tobacco Product Regulation." Specifically, the WHO stated that despite the fact that these flavored products have not been extensively studied:

> the introduction of new flavoured tobacco products raises *serious public health concerns*. Preliminary research on patterns of flavoured cigarette use shows that younger smokers are more likely than older smokers to try flavoured cigarettes. Further, other flavoured tobacco products may be associated with increased use and interest among younger smokers.[67]

The WHO concludes:

> Basic public health principles dictate that flavours should not be used to adulterate contaminated food or to make drugs having a high potential for dependence more enticing. The popularity of these products with youths, combined with the need for strict adherence to these principles, *warrants action*.[68]

Appeal to Youth") Exhibit US-40; Klein, *et al.*, "Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004-2005," Nicotine & Tobacco Research, vol. 10, No. 7, at 1213 (July 2008) ("Findings from this study suggest these products will likely find their largest market share among adolescents and young adults. Virtually all tobacco users become addicted before they can truly understand the consequences. Adding flavorings to tobacco products to make what is admittedly a dangerous and addictive product more appealing *would seem to be harm enhancing and should be prohibited*.") (emphasis added) ("Klein Article"), Exhibit US-51.

[65] Indonesia Opening and Closing Statement, para. 16.

[66] *See* Indonesia First Written Submission, para. 102; Indonesia Opening and Closing Statement, para. 16.

[67] WHO, *The Scientific Basis of Tobacco Product Regulation*, at 38, Exhibit US-113.

[68] WHO, *The Scientific Basis of Tobacco Product Regulation*, at 39 (emphasis added), Exhibit US-113. The United States would further note that the NGO community has attacked these products as appealing to young people, particularly children. *See, e.g.*, Campaign for Tobacco-Free Kids Press Release, "Cuddle Up With Cancer: RJR's Candy-Flavored 'Winter Blend' Cigarettes Show Big Tobacco Hasn't Changed" (November 16, 2004), Exhibit US-125; *see also* WHO, *The Scientific Basis of Tobacco Product Regulation*, at 25 ("The current lack of regulation of these products is of considerable concern to the tobacco control community."), Exhibit US-113. In addition, the attorney generals of 40 U.S. states also agree with this assessment. *See* RJ Reynolds Consent Decree, at 1, sec. II.1.A (requiring RJ Reynolds to cease manufacturing, marketing, distributing, and selling its current flavored cigarette brands from the market based on the attorney generals determination that the company had violated the Master Settlement Agreement's prohibition against targeting youth in the marketing and advertising of tobacco products), Exhibit US-61.

2. Clove Cigarettes Also Raise Serious Public Health Concerns

46. The WHO has specifically recognized that "younger smokers are more open to unique and exotic flavors."[69] Clove cigarettes not only have a distinctive odor and taste that is pungently sweet, such characteristics are trumpeted by the Indonesian producers.[70]

47. Like the other banned products, clove cigarettes are purposively designed to have these attributes. As discussed previously, Indonesian producers include a "secret sauce" that "soften[s] the bite of tobacco and the pungency of clove."[71] Indonesian producers also add a "sweetened" tip to create "a rich[] and fruity taste, sweet-scented aroma and pleasant aftertaste," *in contrast* to "regular cigarettes."[72] These attributes are further heightened when Indonesian producers add additional candy and fruit flavors, such as chocolate, coconut, and strawberry, to their product.[73]

48. Given these similarities between clove cigarettes and the other cigarettes banned under section 907(a)(1)(A), it is not surprising that clove cigarettes also are disproportionately used by young people just as are the other banned cigarettes.[74] For all these reasons, there is no sound public health reason to distinguish between clove cigarettes and the other banned flavored cigarettes.

49. The WHO Report explicitly confirms this view when it recognizes that flavors, "such as cherry and cloves can be used to appeal to target populations," and considerations such as these should "provide the foundation for potential restrictions on designs and ingredients that enhance such potential and appeal." The WHO Report states, in full:

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[69] WHO, *The Scientific Basis of Tobacco Product Regulation*, at 27 (citing *New Cigarette Brands with Flavors that Appeal to Youth*, Exhibit US-40), Exhibit US-113.

[70] U.S. First Written Submission, para. 36; *see also Flavoured Cigarettes, Sensation Seeking and Adolescents' Perceptions of Cigarette Brands*, at 459 ("It is known that sweet flavours encourage trial of unfamiliar foods and are particular palatable to youths."), Exhibit US-123.

[71] U.S. First Written Submission, para. 36 (quoting Demirtas, "Djarum Cigarettes & Cigars," Exhibit US-39).

In this regard, Indonesia's claim that the "secret sauce" is "very similar to the flavoring ingredients used in American blend cigarettes" is seriously misleading. Indonesia Answer to Q29, para. 74. Cigarettes that include additives such as vanilla and sugar are allowed to be produced and sold to the extent that those additives do not give the product a characterizing "sweet" flavor. Clove cigarettes apparently have such a characterizing flavor (in addition to having the characterizing flavor of clove). The products allowed to be sold under section 907(a)(1)(A) have a characterizing flavor of either tobacco or menthol. If a product has other characterizing flavors, including the flavors of vanilla or sugar, they are banned under U.S. law, regardless of origin.

[72] U.S. First Written Submission, para. 36 (quoting Demirtas, "Djarum Cigarettes & Cigars," Exhibit US-39).

[73] U.S. First Written Submission, para. 37 (citing Exhibits US-39, 40). In this regard, we note that Indonesia's Answer to Q34 that "[t]here are no reports of cocoa being used in clove cigarettes" is misleading, given the existence of chocolate flavored clove cigarettes. *See* U.S. First Written Submission, para. 36.

[74] Exhibit US-53, at 7; U.S. First Written Submission, section III.F (summarized at para. 55); Opening Statement, para. 16.

Main Recommendations

The harm caused by tobacco products is a function of their toxic emissions as well as the extent and patterns of their use. *Patterns of use, in turn, are related to dependence potential and consumer appeal*. The tobacco industry's documents and expert evaluation reveal extensive manipulation of contents and designs to increase dependence potential and appeal. For example, the dependence-causing effects of nicotine can be increased by contents and designs that increase the free base fraction of nicotine, and flavourings *such as cherry and cloves* can be used *to appeal* to target populations.

It is recommended that tobacco product *contents and designs* be evaluated from the perspective of dependence potential and *consumer appeal* to provide *the foundation for potential restrictions on designs and ingredients that enhance such potential and appeal*.

Significance for public health policies

The significance for public health policies includes maintaining, increasing, and implementing *standards for the contents, designs and emissions* of tobacco products that relate to dependence potential and *consumer appeal*, thereby supporting efforts to reduce the prevalence of use and possibly toxicant intake among users. Combined with other elements and actions of tobacco control, such policies should lead to a reduction in tobacco use and associated disease.[75]

E. The Reliable Survey Data Contradicts Indonesia's Factual Assertions

50. Indonesia contends that clove cigarettes do not appeal to youth at all,[76] and that the United States is "dead wrong" to suggest otherwise.[77] But stridency cannot replace evidence, and the evidence belies Indonesia's contentions.

51. As the Unite States has established, the reliable survey data from recognized, nation-wide studies recognize that cigarettes with characterizing flavors of candy, fruit, clove, etc. not only appeal to young people, but appeal (and are used) disproportionately so.[78] As discussed above, the

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[75] WHO, *The Scientific Basis of Tobacco Product Regulation*, at 99 (emphasis added), Exhibit US-113.

[76] *See, e.g.*, Indonesia First Written Submission, at para. 94 ("In 2007, only .1% of youth smokers used clove cigarettes and by 2008 that number had fallen to zero.").

[77] Indonesia Opening and Closing Statement, para. 109.

[78] Exhibit US-53; U.S. First Written Submission, section III.F.

WHO has endorsed the fact that these flavored cigarettes – including clove cigarettes – do appeal to young smokers, directly undermining Indonesia's position.[79]

52. Given the importance of the issue of whether the banned products were being used disproportionately by young people in the United States, the United States would like to address Indonesia's improper use of the data drawn from reliable sources as well as its use of data from unreliable sources.

1. Indonesia's Approach Does Not Present a "Fair Comparison"

53. Indonesia claims that its use of 2007 and 2008 NSDUH data is "necessary to make a fair comparison" to compare usage of menthols and clove cigarettes.[80] That assertion is not correct.

54. As an initial matter, the United States notes the importance of the use of prevalence data. The appropriate first step in addressing any public health problem is understanding the scope of the problem. That is, how many people are affected by the problem. In this case, how many people smoke? Thus, when the United States uses the term "prevalence," we are referring to the percentage of a given population who is using (or has used) cigarettes or a particular type of cigarette. For example, based on the data presented by the United States, the Klein article states that 23% of 17 year olds have used flavored cigarettes in the month prior to the study being conducted.[81] This is the prevalence of use.

55. The best way to assess prevalence is to ask if an individual has used a specific cigarette in the past month (or year). The surveys relied upon by the United States to demonstrate the use of clove cigarettes by youth – the 2002 and 2003 NSDUH, the Monitoring the Future ("MTF"), and the National Youth Tobacco Survey ("NYTS") – all do this.

56. Indonesia, however, would like to look at only those people who said that they have smoked clove cigarettes "most often (that is, more than any other type of cigarette)." However, this approach flies in the face of how the product is actually used. We know that people who smoke flavored cigarettes, including clove cigarettes, generally do so infrequently or only on special occasions.[82] This fact does not minimize the importance of clove cigarettes in the initiation of smoking behaviors. However, it does mean that only including people who smoke clove cigarettes "most often" is an inappropriate way to understand their use to understand their use of these cigarettes. Specifically, to the extent that there is concern that smoking clove cigarettes contributes to the addiction of individuals to cigarettes, the total prevalence of use (not prevalence of heavy use) is the most relevant metric.

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[79] WHO, *The Scientific Basis of Tobacco Product Regulation*, at 99, Exhibit US-113.

[80] Indonesia Opening and Closing Statement, para. 113.

[81] *See* Klein Article, Exhibit US-51.

[82] *See* U.S. First Written Submission, paras. 182-189; Exhibit US-53, at 10.

57. By way of example, consider a survey that asked drug users, "Which drug did use you use most often in the past month-cocaine, heroin or marijuana?" A typical response might be: 60% of respondents to this survey said marijuana, 35% of people said heroin and 5% said cocaine. Based on how Indonesia has analyzed the cigarette surveys, Indonesia would conclude that only 5% of drug users used cocaine. However, the survey was not designed to, and could not, answer that question. The only way to establish the prevalence of cocaine use among drug users is to ask, "Did you use cocaine in the past month?"

58. In short, Indonesia chooses an inappropriate approach to data analysis, and ignores how clove cigarettes are used in the real world. In order to understand how many people used clove cigarettes, the survey needs to ask: "Did you smoke a clove cigarette?" Indonesia's approach does not do that. In contrast, the three surveys that do are the MTF, the NYTS, and the 2002-2003 NSDUH.[83] As discussed previously, these surveys provide strong support for the United States view of consumer use of cigarettes.[84]

2. Indonesia's Conclusions of the Percentage of Adolescents That Smoke Cloves Is Inaccurate

59. One particularly egregious result of Indonesia's misuse of the recent NSDUH data as discussed above is Indonesia's conclusion that 0.09% of the clove cigarettes smoked in the United States during 2007 were smoked by people under the age of 18.[85]

60. To arrive at the conclusion that only 0.09% of clove cigarettes smoked in 2007 were smoked by youth, Indonesia looks at those who said that they smoked clove cigarettes "most often" and then multiplies by the number of days they smoke and how many cigarettes per day. To present this more accurately, Indonesia should have said, "People under the age of 18 who said that they smoke clove cigarettes most often smoke 0.09% of the clove cigarettes in the United States."[86]

61. What is obvious when presented this way is that Indonesia's figure does not count the vast majority of adolescents who smoke clove cigarettes, because most do so occasionally, and not as their primary cigarette.[87] Accordingly, there is a large number of cigarettes smoked by youth that are not included in Indonesia's number. While an exact calculation cannot be done with existing

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[83] *See* U.S. First Written Submission, section III.F (discussing the relevant surveys).

[84] *See* U.S. First Written Submission, paras. 54-55 (summarizing Exhibit US-53); U.S. Opening Statement, paras. 16-19 (summarizing the U.S. position)

[85] Indonesia Answer to Q17, para. 50.

[86] Even then, though, the United States has further concerns about the methodology that was used; these further concerns are outlined in the U.S. First Written Submission, paras. 71-75.

[87] *See* Exhibit US-53, at 10; U.S. First Written Submission, paras. 182-189.

data, it is certainly much larger that the number claimed by Indonesia. When young adults are included – as they should be, given that they are still in the "window of initiation" – it is clear that Indonesia cannot support its contentions that, e.g., "clove cigarettes do not appeal to youth at all."

3. Indonesia's Comparison of Raw Numbers – Instead of Relying on Prevalence – Results in Inaccurate Conclusions

62. At several different parts of its argument, Indonesia appears to misunderstand the United States when it contends that the banned products are used "overwhelmingly" or "disproportionately" by young people.[88] Indonesia appears to believe that the United States is talking in terms of raw numbers, and counters that of people that smoke cloves, more are older than 18 than younger.[89] Again, Indonesia considers this to be "a more accurate comparison."[90]

63. As discussed earlier, the United States has presented data on the prevalence of use. That is, for a given group (such as youth, or young people, or adults), what is the percentage of the population of that group that used the product in the past month (or year, in some surveys). This is because all tobacco products used by an individual contribute to the addiction of that person.

64. Indonesia, in contrast, prefers to compare the number of youth that use clove cigarettes to the number of adults that use clove cigarettes. Getting away from the actual numbers that they use (our expanded critique of how Indonesia misuses survey data was presented above), the concept of comparing the number of youth who use a product to the number of adults who use a product is fundamentally flawed for the simple reason that there are vastly more older adults (age 26 and older) that there are young people (age 12-25). Though the age groups differ slightly, numbers from the United States Census Bureau estimate that in 2000 there were 60 million Americans age 10-24 and 180 million Americans age 25 and above. Looked at another way, there are 209 million Americans age 18 and above and 31 million Americans age 10-17.

65. With data presented this way, it is no wonder that Indonesia wants only to look at the sheer numbers. What is important to remember, though, is that young people grow up and addictions that are acquired during this window of initiation will persist. Thus, products that are used by a significant percentage of young people and will contribute to the development of a lifelong, addictive and deadly habit and are appropriate targets for public health interventions.

4. Indonesia Is Wrong to Minimize the Impact of Clove Cigarettes

66. Indonesia repeatedly – and in the U.S. view wrongly – minimizes the contribution of clove cigarettes to the addiction of millions of youth. For example, in Indonesia's response to the

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[88] *See, e.g.*, U.S. Answer to Q12(d), para. 24.

[89] *See* Indonesia Opening and Closing Statement, para. 116.

[90] Indonesia Opening and Closing Statement, para. 115.

Panel's Question 12(e), Indonesia states that the "prevalence of clove smoking is minuscule … in the United States."[91] The United States has presented a number of studies demonstrating that the use of clove cigarettes is anything but minuscule, especially among young people. For example:

- According to the NYTS, 10% of smokers in 2009 aged 12-21 smoked clove cigarettes in the past month;[92] and
- According to the Monitoring the Future surveys, almost 6% of 12th graders in 2009 reported smoking clove cigarettes in the past year.[93]

67. These numbers represent a legitimate target for public health interventions. Given the highly addictive and deadly properties of cigarettes, Indonesia is wrong to trivialize these numbers when they have the potential to contribute to the addiction of millions of additional individuals to a product that may kill them. Unless adolescent smoking prevalence changes, an estimated 19 million individuals currently under the age of 18 will grow up as addicted adult smokers.[94] Given the data from the NYTS, clove cigarettes will contribute to the addiction of almost 2 million current youth.

68. In the way it presents information regarding section 907(a)(1)(A), Indonesia also attempts to minimize the public health problem of non-menthol flavored cigarettes by asking the Panel to consider each flavor separately, or at least cloves separately from cherry, chocolate, liquor, and other non-clove flavors. The Klein Article found that almost 23% 17 years olds used flavored cigarettes.[95] The study itself shows that not all of them would use all varieties of flavored cigarettes, but that in no way lessens the problem being addressed.

5. Indonesia's Attempts to Minimize the Importance of the Klein Article Are Unfounded

69. As discussed previously, the Klein Article analyzed two different surveys addressing whether adolescents and young adults were using the new flavored products. The survey asked respondents if they had smoked any one of three of the most popular brands of flavored cigarettes (Camel Exotic Blends, Kool Smooth Fusions and Salem Silver Label) that include many sub-brands in each.[96] The study found that almost 23% of 17 year olds had smoked at least one of the

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[91] Indonesia Answer to Q12(e), para. 43.

[92] Exhibit US-53, at 2.

[93] Exhibit US-53, at 3.

[94] U.S. First Written Submission, para. 18.

[95] Klein Article, at table 2, Exhibit US-51.

[96] *See* Klein Article, at 1210 (stating the Camel Exotic Blends line included such flavored products as Crema, Twist, and Dark Mint. Kool Smooth Fusion cigarettes include flavors such as Mocha Tobacco and Midnight Berry. Salem Silver Label cigarettes include flavors such as Salem Dark Currents and Fire & Ice.), Exhibit US-51.

three in the past 30 days. It also found that the use of flavored cigarettes rapidly dropped off among older age groups; for example, only 0.8% of individuals older than 55 had smoked one of the three during that same period of time.[97]

70. Indonesia attempts to minimize the importance of the Klein Article in two ways, neither of which is well-founded.

71. First, Indonesia claims that because two of the three flavored brands asked about in the study contain menthol (Kool Smooth Fusion and Salem Silver Label) in addition to the other flavors, that menthol is the appealing flavor.[98] The data in the study shows otherwise. Among respondents (age 17-26) to the survey, 10.5% said that they smoked the Camel Exotic Blends cigarettes (which are non-menthol), 1.1% smoked the Kool Smooth Fusion cigarettes and 1.8% smoked the Salem Silver Label cigarettes. This means that approximately three to four times as many people in this age range smoked the non-menthol flavored cigarettes as smoked the menthol cigarettes that have additional characterizing flavors. Thus, when an actual examination of the data is performed, the opposite conclusion is reached from what Indonesia claims.

72. Second, Indonesia attempts to minimize the Klein Article by stating that it means that 75% of 17 year olds had not smoked one of the three flavored brands.[99] By doing so, Indonesia appears to trivialize the impact of a deadly, addictive product. Current estimates are that 19 million youth in the United States today will grow up to be addicted lifelong smokers and more than 6 million of them will die prematurely from smoking.[100] If flavored cigarettes play a role in addicting 25% of these youth, that would mean that they played a role in the deaths of around 1.5 million people who started smoking as young people. Hardly a small figure.

6. Western Wats Survey Does Not Provide Reliable Data

73. Indonesia relies upon a survey contained in Exhibit IND-26, a volunteer online panel that was conducted by a private company formerly named Western Wats (now apparently called "Opinionology"), as part of Indonesia's defense (hereinafter the "Western Wats survey").[101] In

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[97] Klein Article, at table 2, Exhibit US-51.

[98] *See* Indonesia Opening and Closing Statement, para. 85 ("The U.S. claims that the Klein Study . . . shows that more youth than adults were smoking cigarettes with a characterizing flavor, other than tobacco or menthol, when the ban took effect. But 2 out of the 3 flavored brands tested in this study for popularity with youth were menthol-based flavors (Kool Fusion and Salem Silver). Thus, to the extent the Klein Study proves anything, it proves that menthol is the flavoring that appeals most to youth."); Indonesia Answer to Q43, para. 96.

[99] Indonesia Opening and Closing Statement, para. 110 ("[T]he only age group surveyed in the 'youth' segment, defined as under 18, was 17 years old. The researchers found that, while 17-year-olds had the highest rate of having used one of the three flavored cigarettes studied, that rate was only 22.8 percent. That means that more than 3 out of 4 17-year-old smokers were NOT using the flavored cigarettes that were the subject of the study.").

[100] U.S. First Written Submission, para. 18.

[101] *See* http://www.opinionology.com/.

particular, in response to the Panel's Question 61, Indonesia states that the Western Wats survey "show[s] that clove smokers began smoking brands other than clove and tried clove cigarettes more than two years after their first cigarette"[102]

74. The United States has significant concerns about any scientific conclusions drawn from this online survey, including Indonesia's statement above. It is important to contrast Indonesia's reliance on online surveys and its inappropriate uses of other surveys with the U.S. reliance on data from well-established national surveys that use representative samples of the U.S. population. Although collecting data using volunteer online panels is becoming more popular, it can present significant methodological flaws. These flaws undermine the conclusions that can be drawn from the results.

75. The first major issue is that online panels like the one conducted by Western Wats do not recruit members using standard probability-based recruitment. Instead, panel companies like Western Wats typically put invitations to join in front of as many people as possible, using techniques like: banner advertisements on websites; email invitations to lists of email addresses collected by websites; advertisements on sites that offer access to a number of online merchants; and advertisements next to search engine results. This is distinct from recruitment in traditional probability-based surveys (like the ones presented by the United States) where there is a defined sampling frame and each element of the frame has a known probability of selection. Surveys like Western Wats typically take whoever they can find, whereas probability-based surveys have previously identified all the groups and subgroups that need to be included in the survey, calculated expected response rates, and identified the sampling plan to ensure that the relevant populations will be included in the survey. Consequently, for the survey like the one conducted by Western Wats, traditional statistical techniques, such as confidence intervals and tests of statistical significance, cannot be used.

76. A second major issue is related to the form of the survey. Because of the Western Wats web-centric nature, volunteer online panels necessarily fail to represent individuals who do not access the internet and presumably under-represent individuals who use the internet less. These biases are likely to be most severe for older adults. Unlike regular surveys, where an individual is directly contacted and asked to participate in a survey, online panels typically require a "double opt-in" process whereby individuals who see an advertisement or receive an invitation must first visit the website and provide information about themselves and then respond to a confirmation email. These processes act as additional screens, likely leaving out all but the most compliant individuals.

77. A paragraph from a report by the American Association for Public Opinion Research ("AAPOR") summarizes the issues with online polls:

[102] Indonesia Answer to Q61, para. 129.

> Researchers should avoid nonprobability online panels when one of the research objectives is to accurately estimate population values. There currently is no generally accepted theoretical basis from which to claim that survey results using samples from nonprobability online panels are projectable to the general population. Thus, claims of "representativeness" should be avoided when using these sample sources. Further, empirical research to date comparing the accuracy of surveys using nonprobability online panels with that of probability-based methods finds that the former are generally less accurate when compared to benchmark data from the Census or administrative records. From a total survey error perspective, the principal source of error in estimates from these types of sample sources is a combination of the lack of Internet access in roughly one in three U.S. households and the self-selection bias inherent in the panel recruitment processes.[103]

78. While Internet surveys may be useful in some contexts, the conclusions drawn by Indonesia from the Western Wats survey do not meet rigorous scientific standards and they should not be relied upon by the panel in a decision-making capacity.

F. The Serious Public Health Concern Resulting From the Production and Sale of the Now Banned Cigarettes Required the United States to Act

79. As noted previously, the Master Settlement Agreement ("MSA"), which went into force in 1998, restricted the ability of cigarette companies to directly target adolescents in their advertising and marketing.[104] The companies reacted to these new restrictions by significantly increasing advertising in print magazines that have strong readership among young people, as well as ratcheting up other ways to reach customers, including direct mailings, web sites, and promotions at bars and similar venues.[105] Much of this conduct was directed at young adults, who, as discussed above, are a key demographic for the companies.[106] The major U.S. companies spent US$11.2 *billion* dollars in advertising and promotional activities in 2001, a 98% increase over

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[103] AAPOR Report on Online Panels, at 52 (March 2010), Exhibit US-126.

[104] U.S. First Written Submission, paras. 82-88.

[105] *See, e.g.*, *Acceptable Rebellion*, at 214-217, Exhibit US-96; *Bar and Nightclub Tobacco Promotions That Target Young Adults*, at 414-419, Exhibit US-101; *Why and How the Tobacco Industry Sells Cigarettes to Young Adults*, at 912, Exhibit US-93.

[106] *See* U.S. Second Written Submission, section II.D.

1997 pre-MSA spending.[107] RJ Reynolds, in particular, was 57% more likely to place ads in the magazines with higher youth readership than it was in 1997.[108]

80. RJ Reynolds flavored Camel Exotic Blends appears to be a significant element of RJ Reynolds' post-MSA plan to retain – and increase – its market share among young people, and the product line was heavily marketed and advertised through a variety of sources, including promotional gifts and Moroccan themed "Casbah" events at bars popular with young adults.[109] Later product lines were also released with the backing of similar marketing plans, including RJ Reynolds' launch of its "winter blend" cigarettes in 2004 that featured toffee and mocha mint flavored cigarettes.[110] Although RJ Reynolds lead U.S. producers in marketing these new flavored products, other cigarette companies – including Indonesian manufacturers of clove cigarettes – took the same approach. For example, PJDjarum was marketing clove cigarettes with additional candy flavors, such as cherry and vanilla, to its already during the years leading up to the enactment of the section 907(a)(1)(A) – a point that Indonesia denies[111] – but is unquestionably true.[112]

81. In 2006, the MSA state attorneys general agreed not to bring suit against RJ Reynolds for violating the MSA in connection with the marketing and advertising of flavored cigarettes in exchange for a variety of concessions from the companies, including withdrawing their current non-tobacco, non-menthol flavored products from the markets of the 40 MSA states.[113] As discussed previously, however, the 2006 Consent Decree only applied to RJ Reynolds, and in any event, did not prohibit RJ Reynolds from marketing *new* flavored cigarette brands in any of the 50 U.S. states.[114] And, in fact, just seven months later RJ Reynolds launched an entirely new

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[107] Lewis, *et al.*, "Tobacco Industry Direct Marketing After the Master Settlement Agreement," Health Promotion Practice, supp to July 2004, vol 5, no. 3, at 76S ("Tobacco Industry Direct Marketing Post MSA"), Exhibit US-127; *see also* Chung, *et al.*, "Youth Targeting By Tobacco Manufacturers Since The Master Settlement Agreement," Health Affairs, 21, no.2 (2002): 254-263, at 258 ("From 1 January 1997 to 31 December 2000, an estimated [US]$1.01 billion was spent to place 12,0000 cigarette ads in the thirty-six magazines in our sample.") ("Youth Targeting By Tobacco Manufacturers Since the MSA"), Exhibit US-128.

[108] *Youth Targeting By Tobacco Manufacturers Since the MSA*, at 258-259, Exhibit US-128.

[109] *Tobacco Industry Direct Marketing Post MSA*, at 76S-79S, Exhibit US-127. Camel Exotic Blends marketing also included a "controlled circulation" magazine, which featured recipes for alcoholic drinks and which flavored cigarette would go best with which drink. *Id.* at 77S.

[110] *Cuddle Up With Cancer: RJR's Candy-Flavored "Winter Blend" Cigarettes Show Big Tobacco Hasn't Changed*, (noting that the line was being heavily marketed in magazines with a young readership, including Rolling Stone, Glamour, Cosmopolitan, and Elle), Exhibit US-125.

[111] *See* Indonesia Answer to Q62, para. 130 ("An analysis of this question is not relevant to Indonesia's claims given that candy-flavored cigarettes are domestically produced and, thus, a ban on them is not trade-restrictive.").

[112] *See* U.S. First Written Submission, paras. 37.

[113] *See* U.S. First Written Submission, paras. 89-92.

[114] *See* U.S. First Written Submission, paras. 93-95; *See also* 2006 Consent Decree, Exhibit US-61.

flavored cigarette line, the Camel Signature Blends line, to be sold throughout the United States.[115] This line included "Robust," which had flavorings "similar to the notes found on cocoa and espresso" and "Infused," which was accented with "notes of citrus" and had "a sweet apple-like flavor."[116]

82. The cigarette companies have proven themselves to be flexible, opportunistic, and fiercely competitive market actors, and it is well-established that they will take advantage of whatever opportunity the law allows them to market their products to young people, the key demographic for the companies. The 2006 Consent Decree provided such an opportunity by continuing to allow all companies – including the signatory, RJ Reynolds – to market cigarettes flavored with candy, fruit, spices, etc. The production and sale of such products were not prohibited in the United States until section 907(a)(1)(A) entered into force on September 22, 2009.

G. Section 907(a)(1)(A) Affects Both Foreign and Domestic Products

83. Indonesia continues to contend that no U.S. produced flavored cigarettes were on the market in 2009, meaning, in Indonesia's view, that the only products banned by the measure were foreign products, in particular, Indonesia's products.[117] Indonesia relies heavily on this allegation – it runs through both its national treatment and TBT Article 2.2 claims – and attributes legal significance to this allegation, which it claims to be true. Indonesia actually goes as far as to claim that the United States has conceded this point.[118] The United States has not. In fact, it appears that at least one U.S. producer was selling clove flavored cigarettes into September of 2009.[119]

84. The actual fact is that U.S.-produced flavored cigarettes other than tobacco or menthol were on the market as recently as one year before section 907(a)(1)(A) went into effect, and even if it *were* the case that they disappeared by 2009, there is no guarantee apart from section 907(a)(1)(A) that they would have been off the market for long. As the United States has demonstrated, U.S. companies had 26 flavored products on the market in 2008 compared to 19 products being sold by foreign companies (17 of which were be Indonesian).[120] It may be in fact

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[115] Campaign for Tobacco-Free Kids Press Release, "RJ Reynolds Launches New Flavored Cigarettes Circumventing Settlement With State Attorneys General" (May 22, 2007), Exhibit US-129; *Acceptable Rebellion*, at 217, Exhibit US-96.

[116] *RJ Reynolds Launches New Flavored Cigarettes Circumventing Settlement With State Attorneys General*, Exhibit US-129.

[117] Indonesia Answer to Q17, para., 48. ("[B]y the time the ban went into effect in 2009, the flavoured cigarettes produced by RJ Reynolds and marketed under Camel, Kool, and Salem brands were no longer being sold in the U.S. and "candy flavoured" cigarettes had a market share of zero.").

[118] Indonesia Answer to Q17, para., 48.

[119] *See Letter from Larry Sherman to Customers* (September 17, 2009), Exhibit IND-13.

[120] U.S. First Written Submission, paras. 51.

that some of these products remained on the market in 2009, even if discontinued earlier, as retailers sold their purchased stock to customers up until the time it was illegal to do so (*i.e.*, September 22, 2009). Certainly, Indonesia has not put evidence indicating that that is not the case.

85. Moreover, the effect of section 907(a)(1)(A) on U.S. or foreign cigarettes can not be accurately assessed solely by looking at what products were on the market in 2009, immediately before the ban went into effect. Such effect – not surprisingly advocated by Indonesia – fails to take into account the effect of the legislation in the lead up to its taking force. As stated previously, the measure forced U.S. companies to give up an entire product line that they had spent decades developing.[121] Both in the First Submission and further in this submission, the United States presents significant evidence based on the internal corporate documents of the U.S. cigarette companies themselves that they had developed this product line for decades.[122] Indonesia has not contested this fact, leaving the issue, thus far, completely unrebutted.

86. The United States would also note that it is not unusual for a company to withdraw its product from the market where the government is strongly considering whether to ban that product. Two recent examples of this occurring in the United States are in regard to bisphenol A ("BPA"), a chemical that is present in many plastics,[123] and infant cribs that with sides that move up and down.[124] Moreover, the fact that the marketplace reacted preemptively to an impending ban cannot affect the analysis of whether a Member has acted consistently with its WTO

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[121] *See* U.S. Answer to Q17, paras. 45.

[122] U.S. First Written Submission, paras. 43-53; U.S. Second Written Submission, section II.D.

[123] BPA is a chemical that is present in many plastics, including infant bottles and the lining of many containers used to ship and store food products. FDA, Environmental Protection Agency ("EPA"), and other federal agencies expressed concern about the potential negative impact of BPA on various organ systems in fetuses and children. FDA News & Events, "Update on Bisphenol A for Use in Food Contract Applications: January 2010," http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm; EPA, Bisphenol A (BPA) Action Plan Summary, http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/bpa.html. Additionally, in 2009 legislation was introduced in Congress that would restrict the use of BPA. Senator Feinstein Press Release (March 13, 2009), http://feinstein.senate.gov/public/index.cfm?FuseAction=NewsRoom.PressReleases&ContentRecord_id=01832cd5-5056-8059-76db-c984d14b7fce. At this point in time, however, no agency has taken regulatory action against BPA and Congress has passed no law. However, given the possibility of federal action, manufacturers have already taken steps on their own, including the voluntary removal of BPA from baby bottles and certain other products.

[124] Drop-side cribs, which had been linked to a number of infant deaths in the United States, have recently been removed from the marketplace in the United States. In December 2010, the U.S. Consumer Product Safety Commission ("CPSC") approved a regulation to prohibit the sale, manufacture or resale of cribs of this type in the United States. *See* Associated Press, "After dozens of deaths, drop-side cribs outlawed," (December 15, 2010), http://www.msnbc.msn.com/id/40678788/ns/health-kids_and_parenting/; *see also* CPSC Rule, re Cribs, http://www.cpsc.gov/businfo/frnotices/fr11/cribfinal.pdf. However, the organization that sets voluntary industry standards, ASTM International, had previously approved a ban on drop side cribs. Moreover, even in advance of proposed regulations, manufacturers had begun phasing out drop-side cribs. USA Today, "Feds push 'drop-side' crib ban as Pottery Barn issues recall," (July 14, 2010), http://www.usatoday.com/news/health/2010-07-14-crib-safety_N.htm.

obligations. If that were the case, then the same measure, enforced by two different Members, could be found both to be consistent and inconsistent based solely on the actions (or non-actions) of that Member's domestic industry in the lead up to a measure taking force.

II. LEGAL ARGUMENTS

A. National Treatment Claims under Article III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement

1. Introduction

87. In adopting the WTO's national treatment obligation, Members recognized that internal measures "should not be applied to imported or domestic products *so as to afford protection to domestic production*."[125] The national treatment obligations contained in Article III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement are intended to prevent measures that either expressly discriminate against foreign products (*de jure*), or are facially neutral but, in fact, are a pretext or proxy for doing so (*de facto*). These national treatment obligations are *not* intended to prevent legitimate measures, such as section 907(a)(1)(A), that establish neutral product standards based on public health criteria.

88. Throughout its submissions and statements, Indonesia has attempted to belittle or ignore both the relevant facts in this case and the context of the provisions at issue. Indonesia has characterized section 907(a)1(1)(A) incorrectly as merely a "ban on clove cigarettes"[126] whose "sole purpose" is to affect the sale and distribution of cloves.[127] Indonesia has denied that clove cigarettes are unique or special because of the presence of clove,[128] denied that they are used especially by young people,[129] and denied or scoffed at the fact that section 907(a)(1)(A) addresses what is unquestionably a serious and deadly public health problem, smoking by young people in the United States.[130] None of these denials is substantiated by facts.

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[125] GATT 1994, Article III:1 (emphasis added).

[126] *See*, *e.g.*, Indonesia First Written Submission, paras. 11, 12, 103, 111, 131, 132, 147, 152, 154. Indonesia Opening and Closing Statement, paras. 20, 46, 146.

[127] *See*, *e.g.*, Indonesia Opening and Closing Statement, paras. 46, 53.

[128] *See*, *e.g.*, Indonesia Opening and Closing Statement, para. 93 (accusing the United States of "manufacturing" differences between "clove cigarettes and domestically produced cigarettes"); Indonesia Answer to Q29, para. 74 (claiming without evidence that the closely guarded and widely touted "secret sauce" in clove cigarettes is "very similar to the flavoring ingredients used in American blend cigarettes...").

[129] *See*, *e.g.*, Indonesia Opening Closing Statement, para. 109.

[130] Indonesia Opening and Closing Statement, para. 74 ("I want to say as clearly as I can, this is all a bunch of nonsense. At most, it's a post-hoc rationalization crafted by some lawyers."); para 80 ("They're just making it up."); and para 82 ("The bottom line is [the United States is] making this stuff up as they go along. It's all, or mostly, post-hoc rationalizations ...").

89. Section 907(a)(1)(A) draws legitimate distinctions among types of cigarettes based on what is appropriate for the protection of the public health in the United States. Whether flavors are banned or not banned has nothing to do with the national origin of cigarettes containing different flavors. Clove is included among the banned characterizing flavors because, like cherry, chocolate and other flavors, it is "used to appeal to target populations"[131] and used by young people within the window of initiation (thus facilitating addiction) but whose precipitous prohibition would not cause negative consequences.

90. Indonesia also seeks to sweep away the relevance in this dispute of cigarettes with other characterizing flavors covered under section 907(a)(1)(A), such as variations of spice, fruit, liquor, etc.[132] The fact that section 907(a)(1)(A) also protects American consumers from these domestically-produced flavored cigarettes undermines Indonesia's central claim that section 907(a)(1)(A) targets Indonesian cigarettes; therefore, Indonesia simply asks that the Panel ignore it. However, the U.S.-produced cigarettes with characterizing flavors banned under section 907(a)(1)(A) are relevant in each phase of the national treatment analysis.

91. Clove cigarettes *are* unique cigarettes, unlike tobacco and menthol, most importantly in terms of their relevant physical properties and how they are used by consumers. The presence of clove in cigarettes makes them especially enticing to young people within the age window of initiation, and facilitates addiction. At the same time, the presence of clove does *not* make clove cigarettes especially enticing to older adults. Older adults were not smoking clove cigarettes anywhere near as prevalently as young people in the United States. This distinction is significant – it sets clove cigarettes apart from tobacco and menthol cigarettes. In fact, this distinction is fundamental to the examination of the issues in this dispute – both because it means that clove cigarettes are not "like" tobacco or menthol cigarettes (which have much higher use among adults), and because it shows that section 907(a)(1)(A) does not accord "less favorable treatment" to cigarettes from Indonesia.

2. Contextual Significance of the GATT 1994 and the TBT Agreement to National Treatment Obligations in this Dispute

92. In addition to ignoring relevant facts, Indonesia seeks to ignore or downplay the relevant context of Article III of the GATT 1994 and the TBT Agreement. Contrary to Indonesia's protestations,[133] as the United States previously has discussed, the context provided by Article III:1 of the GATT 1994 is essential to interpreting Article III:4. The Appellate Body articulated that Article III:4 should be interpreted consistently with "[t]he broad and fundamental purpose of Article III [which] is to avoid protectionism in the application of internal tax and regulatory

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[131] *WHO, The Scientific Basis of Tobacco Product Regulation*, at 99, Exhibit US-113.

[132] Indonesia Answer to Q27, para. 71 and Question 49, paras. 103-105; Indonesia Opening and Closing Statement para. 87.

[133] *See*, *e.g.*, Indonesia Opening and Closing Statement, paras. 26-30.

measures,"[134] and with the overarching general principle that measures "should not be applied to imported or domestic products so as to afford protection to domestic production."[135]

93. Moreover, the last sentence of Article III:4 states that "the provisions of this paragraph shall not prevent the application of differential internal transportation charges which are *based* exclusively on the economic operation of the means of transportation and *not on the nationality of the product*." This sentence provides additional context, and supports the principle that Article III:4 prevents measures that discriminate based on the nationality of products, and should not be applied so as to prevent legitimate measures that may have different impacts on different products, both foreign and domestic, but do not discriminate based on the origin of products.

94. In discussing the importance of discrimination based on nationality, the United States is not – as Indonesia suggests[136] – proposing some independent and extraneous text divorced from the text of the WTO Agreement; rather, the United States is simply highlighting a well-established principle that provides important guidance on the interpretation and application of the terms "like product" and "less favorable treatment" as used in the WTO provisions on national treatment.

95. As the United States noted in its Answers to the Panel's First Set of Questions to the Parties, the United States considers that the Panel can consider together the GATT 1994 and TBT national treatment claims, with due consideration to the particular context and requirements of each claim.[137] In fact, the United States submits that the TBT Agreement provides specific context, which is relevant to the national treatment analyses under the TBT Agreement and under the GATT 1994. Accordingly, it is important to consider carefully the particular context of the TBT Agreement as it applies to national treatment.

96. First, the Preamble to the TBT Agreement sets out its object and purpose. Without reciting the entire Preamble, the United States would note the following items as particularly relevant: First, the Preamble states that Members are "*desiring* to further the objectives of the GATT 1994." In other words, the Members contemplated that the TBT Agreement is consistent with the GATT 1994, and its provisions should be read in the context of furthering the objectives of the GATT 1994.

97. Second, the Preamble states that Members are "*desiring* […] to ensure that technical regulations and standards […] do not create unnecessary obstacles to international trade." Implicit in this statement is the understanding and recognition that technical regulations can and do create obstacles to international trade and still are consistent with the Agreement – they just must not do so unnecessarily or in a discriminatory way.

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[134] *EC – Asbestos (AB)*, para. 97; *Japan – Alcoholic Beverages (AB)*, paras. 109, 110, fn 58.

[135] *EC – Asbestos (AB)*, para. 97; *Japan – Alcoholic Beverages (AB)*, paras. 109, 110, fn 58.

[136] Indonesia Opening and Closing Statement, para. 47.

[137] U.S. Answer to Q21(b), paras. 57 and 49, paras. 103-105.

98. Third, the Preamble states that Members "*recogniz[e]* that no country should be prevented from taking measures necessary … for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the level it considers appropriate[…]." This statement confirms the general right of Members to take measures for legitimate objectives, including to protect human health, even when those measures affect or even restrict international trade, so long as certain conditions are met. This statement recognizes that the legitimacy and WTO-consistency of technical regulations that are adopted to meet objectives such as to protect human health or the environment.

99. Other provisions within the TBT Agreement are relevant as well. The TBT Agreement defines a "technical regulation" as a document which lays down product characteristics with which compliance is mandatory;[138] therefore, by definition, technical regulations draw distinctions between and among products which often may have different effects on different products, both foreign and domestic.

100. The repeated theme captured in the Preamble is that technical measures may make product distinctions that affect international trade, so long as certain conditions are met. Thus, as illustrated by the text of the TBT Agreement, Members recognized that technical measures often serve the purpose of prescribing and proscribing product characteristics, requirements and standards, and that such measures may often – legitimately and permissibly – affect international trade and the market access of products, both foreign and domestic. Standing alone, the mere fact that a technical regulation may affect international trade is not evidence that the measure is inconsistent with trade obligations.

101. This layer of context is also relevant in the national treatment analysis under the GATT 1994, as technical regulations are a particular sub-set of the covered measures under Article III:4. Because of the overlapping applicability of very similar national treatment provisions, the United States considers that analyses under each agreement of the same facts and challenged measure must carefully consider, on a case by case basis, the relevant context of each agreement, as they inform and mutually reinforce the other.

3. Like Product Analysis

a. Indonesia Has Failed to Establish That Clove Cigarettes Are Like Tobacco or Menthol Cigarettes

102. As the complaining party, Indonesia has the burden to prove its national treatment claims. Indonesia's burden is not only to provide the factual evidence necessary to support each element of its claims, but also to provide the basic legal argumentation that would attempt to fit the factual

[138] *See* the definition of "technical regulation" in Annex 1 to the TBT Agreement ("Document which lays down product characteristics ...with which compliance is mandatory.").

circumstances presented by Section 907(a)(1) within the framework of the national treatment discipline. Here, Indonesia has met neither its factual or legal burden. In the U.S. First Written Submission, the United States explained that Indonesia had failed to provide facts to support a finding that clove cigarettes are "like" other types of cigarettes.

103. Indonesia's legal argumentation has also proven to be completely deficient. In particular, Indonesia's "like product" analysis is inconsistent – shifting from submission to submission – and without connection to the facts of the dispute or the context provided by the agreements. Indonesia begins in its First Written Submission by noting – as it should – the Appellate Body's statement that the term "like product" "must be interpreted in light of its context, and of the object and purpose, of the provision at issue, and of the object and purpose of the covered agreement in which the provision appears," and that there is no one precise definition of "like product."[139] However, after noting the contextual nature of "likeness," in the immediately following paragraphs Indonesia abandons this principle and invokes the conclusions reached in two disputes with entirely different factual situations as the basis for its claim that "all" cigarettes should be deemed "like" products.[140]

104. In its Answers to the Panel's First Set of Questions to the Parties, Indonesia then makes an abrupt shift – suggesting that all cigarettes are *not* necessarily "like" products.[141] Indonesia offers this characterization in response to a question concerning Indonesia's apparently different, less favorable tax treatment of foreign cigarettes.[142] In response, Indonesia confesses the view that "a case-by-case analysis of likeness in the context of different measures reasonably could conclude that all cigarettes are <u>not</u> like for the purpose of that particular measure." Indonesia assures the Panel that a finding that all cigarettes are "like" in *this* case does not mean that cloves should be considered "like" all other cigarettes in the context of different measures – "different measures" presumably referring tacitly to Indonesia's *own* tax measures. Indonesia appears to maintain, without explanation, that the standard of "likeness" is somehow stricter in the context of its own fiscal measure than for the fiscal measures involved in the disputes Indonesia cites in its First Submission, or in the context of the public health measure at issue in this case.

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[139] Indonesia First Written Submission, para. 48 (quoting *EC – Asbestos (AB)*, para. 88)

[140] Indonesia First Written Submission, paras. 50- 52 (citing *DR – Cigarettes (AB)* and *Thailand – Cigarettes (GATT Panel)*, cases involving tax measures, and not health measures for the proposition that all cigarettes are "like.").

[141] Indonesia Answer to Q47, para. 99.

[142] Question 47 of the Panel's First Set of Questions to the Parties asks "Indonesia submits that 'all cigarettes, especially clove and menthol cigarettes, are like products.' If that is correct, would it not mean that any internal taxes or regulations that accord less favourable treatment to any particular type of cigarette are inconsistent with Article III of the GATT 1994?" The United States considers that the context of this question is Indonesia's preferential tax treatment of domestic clove cigarettes, as noted in the U.S. First Submission, para. 192, fn 246, and the U.S. Answers to Indonesia's First Question, para. 1.

105. Whether all cigarettes are "like" is not the only question on which Indonesia has shifted positions according to what seemed most helpful at the time. In Indonesia's First Written Submission, Indonesia recognized – as it should – that cigarettes with characterizing flavors such as berry or chocolate are relevant to the dispute, and Indonesia included them in its like product analysis.[143] Significantly, Indonesia acknowledged as a legitimate "like product" distinction cigarettes' implications for the public health, which is a primary distinction upon which clove and other characterizing flavors are in fact different from tobacco and menthol. In its first submission, Indonesia wrote:

> other banned additives (*e.g.*, chocolate, strawberry) are what could be fairly called "candy" flavors and were new products developed by cigarette manufacturers and were packaged and marketed to appeal to youth smokers. As such, *they may present a specific health risk by encouraging new, young smokers*. Thus, those cigarettes need not be considered "like" "regular," menthol or clove cigarettes.[144]

Thus, Indonesia expressly recognized that, based on their appeal and, implicitly, the demographics of their users, different cigarettes may pose a different health risk. Moreover, Indonesia recognized that the health risk posed by certain types of cigarettes is so significant in the context of this case that it means that those cigarettes "need not be considered like" other cigarettes. In doing so, Indonesia essentially put what they refer to as "candy" flavors in one "like" category (those that may present a specific health risk by encouraging new, young smokers) and tobacco, menthol and clove flavors in another "like" category.

106. The U.S. First Written Submission showed that clove cigarettes – like the cigarettes with cherry, chocolate and other characterizing flavors mentioned in Indonesia's first submission – presented public health risks due to their appeal to younger smokers.[145] Indonesia then changed its position on flavored cigarettes. At the Panel meeting, Indonesia stated several times that it considers other characterizing flavors entirely irrelevant to this dispute, and in its Answers to the Panel's First Set of Questions Indonesia requested that the Panel remove them from the "like product" and "less favorable treatment" analyses.[146]

107. Through these shifts, Indonesia has shown that it has no coherent legal theory on the like product analysis to be used in this dispute. To the contrary, Indonesia has submitted that all cigarettes are "like," except when an Indonesian fiscal measure might be at issue, and then they probably are not all "like;" and has submitted that cigarettes which pose a different health risk to

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[143] Indonesia First Written Submission, paras. 58, 63.

[144] Indonesia First Written Submission, para. 63 (emphasis added).

[145] Exhibit US-53; U.S. First Written Submission, section III.F.

[146] Indonesia Answer to Q27, para. 71 and Question 49, paras. 103-105; Indonesia Opening and Closing Statement para. 87.

young people need *not* be considered "like" other cigarettes, except if clove cigarettes might be among the cigarettes posing the different health risk, in which case the entire category of non-clove flavored of cigarettes is irrelevant.

108. In addition, Indonesia approaches the four factors suggested in paragraph 18 of the *Report of the Working Party on Border Tax Adjustments* (*i.e.*, physical properties, end-uses, consumer tastes and habits, and tariff classification) as a mechanical exercise, lacking any sort of compass as to which characteristics are relevant and which are not. Indonesia attempts to parse out fine distinctions with respect to the individual factors – for example, by taking pains to argue that physical "properties" and "characteristics" are "at issue," but that "ingredients" are not[147] – but never offers an explanation as to why this matters in this case. And Indonesia has told us that the different experiences consumers derive from smoking (such as pleasure, or, in the case of cloves, the feeling "indulgence" and "something different") are not formally "end-uses,"[148] but has not effectively rebutted that consumers *actually do* experience these differences, or proven that these differences are not relevant. In short, Indonesia lacks a compass with which to guide the comparison as to which qualities and characteristics are relevant. Indonesia has failed to make an *argument*, substantiated with evidence, as to why clove cigarettes are "like" tobacco or menthol cigarettes with respect to the context and circumstances of this case.

b. Clove Cigarettes Are Not "Like" Tobacco or Menthol Cigarettes

109. The covered Agreements and the provisions at issue – Article 2.1 of the TBT Agreement and Article III:4 of the GATT 1994 – provide the context to determine "which characteristics or qualities are important in assessing the 'likeness' of products," "the degree or extent to which products must share qualities or characteristics in order to be 'like products,'" and "from whose perspective "likeness" should be judged."[149] As the Appellate Body notes, the dictionary provides a starting point in defining "like," but leaves many interpretive questions open, and in particular "does not *indicate which characteristics or qualities are important*."[150]

110. The United States underscores here the Appellate Body observation that a "like product" determination cannot simply be rendered by compiling a "laundry list" of similarities and differences as between products; the key interpretive task is to determine which similarities and differences are significant and relevant to determining likeness in this particular case, and for this task, the context of the provisions and Agreements at issue and the factual circumstances of the case are essential.[151] The Appellate Body employs the traditional four factors, but has emphasized

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[147] Indonesia Opening and Closing Statement, paras. 95, 97.

[148] Indonesia Opening and Closing Statement, paras. 106-108.

[149] *EC – Asbestos (AB)*, para. 92.

[150] *EC – Asbestos (AB)*, para. 92 (emphasis in original).

[151] *EC – Asbestos (AB)*, paras. 88, 92, 101-103.

that these four factors are just tools to frame the inquiry,[152] and should not be used as a substitute for the analytical task of determining which factors of "likeness" are relevant in particular circumstances.[153]

111. The United States has set forth the contextual principles of the GATT 1994 and the TBT Agreement that in this case inform a national treatment analysis under those Agreements. In particular, the "like product" analysis should consider not only the nature of the competitive relationship among and between products,[154] but also the basis upon which the technical regulation at issue is based. In this case, the basis for section 907(a)(1)(A) is the protection of public health. To ignore the public health basis of section 907(a)(1)(A) in the "like product" determination would, effectively, ignore the specific context of the TBT Agreement and fail to give effect to the principle that Members can comply with the Agreement where product distinctions serve to protect human health. The like product analysis should apply weight to those characteristics which relate directly to whether the products regulated by the measure are competitive in the U.S. market and which are related to the measure's public health basis.

112. Based on these two guiding principles, the United States submits that certain characteristics are especially relevant to the like product analysis. First, certain physical properties that are different among the compared products should be accorded weight, not only to the extent that they are relevant in assessing the competitive relationship between and among products, but also because they are relevant to the public health basis upon which section 907(a)(1)(A) differentiates among products. Second, consumer tastes and preferences – which stem from the relevant physical characteristics and which have important public health consequences – also should be accorded weight.

113. The physical presence of cloves in clove cigarettes is particularly relevant. The nearly equal mixture of clove and tobacco in clove cigarettes sets them apart to consumers in terms of their taste and aroma.[155] Tobacco and menthol cigarettes do not contain clove, and this difference is directly related to why consumers choose to smoke them, or not. Consumers do not view clove cigarettes as substitutable for tobacco or menthol cigarettes.[156] They select clove cigarettes because they contain clove, and select tobacco and menthol because of the flavor that characterizes those cigarettes. In addition, clove cigarettes contain a "special sauce" that

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[152] *EC – Asbestos (AB)*, para. 102.

[153] *EC – Asbestos (AB)*, paras. 88, 92, 101-103.

[154] U.S. Answer to Q26, paras. 63-65.

[155] U.S. First Written Submission, paras. 36, 163; U.S. Answer to Q38(c), para. 96; Soldz S., Dorsey E., "Youth Attitudes and Beliefs Toward Alternative Tobacco Products: Cigars, Bidis, and Kreteks," *Health Educ Behav* (2005) 32:549, Exhibit US-106.

[156] U.S. Answer to Q38(c), para. 96; Soldz S., Dorsey E., "Youth Attitudes and Beliefs Toward Alternative Tobacco Products: Cigars, Bidis, and Kreteks," *Health Educ Behav* (2005) 32:549, Exhibit US-106.

manufacturers expressly tout as a distinguishing physical feature.[157] Third, clove (and perhaps other flavors in the "special sauce") contains eugenol, which evidence strongly suggests creates a numbing sensation that differentiates cloves from other cigarettes, including menthol.[158]

114. These physical characteristics, unique to clove cigarettes, are directly related to consumer tastes and preferences. Young people within the window of initiation are enticed by the appealing physical characteristics of clove cigarettes,[159] and do not view them as interchangeable with tobacco or menthol cigarettes. These consumer choices and patterns of use also are particularly relevant to the public health basis upon which section 907(a)(1)(A) distinguishes among cigarettes.[160] Section 907(a)(1)(A) is based on the finding that cigarettes with characterizing flavors (other than tobacco or menthol) are especially appealing to young people within the age window of initiation and are much less appealing to older adults.[161]

115. The U.S. position that certain physical traits should carry significant weight because of their relationship to consumer tastes and habits, patterns of use, and the particular public health risk at issue in this case is consistent with the approach in *EC – Asbestos*. For example, in *EC – Asbestos*, the Appellate Body considered each of the four criteria in turn, and then applied weight where it deemed appropriate to conclude that the particular physical characteristic of toxicity was significant in the given circumstances, because it was a basis upon which consumers would differentiate between the products at issue. The Appellate Body considered that the toxicity of chrysotile asbestos to PCG fibres was a health risk which was likely determinant of consumer preference between the products, and these factors pulled strongly toward the Appellate Body's conclusion of "unlikeness" between asbestos and the significantly less toxic PCG fibres.[162] And the relative toxicity of the products was directly relevant to the purpose of the challenged measure, which sought to protect the public health by banning asbestos because of its level of toxicity.[163]

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[157] U.S. First Written Submission, paras. 36, 165.

[158] U.S. First Written Submission, paras. 38, 164; U.S. Answer to Q38(b), paras. 88-94.

[159] U.S. First Written Submission, paras. 35-42, fn 52, 185, Exhibit US-37, Exhibit US-42, Exhibit US-43.

[160] *See, e.g.,* H.R. Rep. No. 111-58 at 38 (2009) "Given that few adult smokers ever use the flavored cigarettes that will be banned and that most adult smokers name other products as their regular brand, it is likely that regular use of these products by heavily addicted adult smokers is negligible;" Exhibit US-67; *see also WHO, The Scientific Basis of Tobacco Product Regulation*, at 26 ("The harm caused by tobacco products is a function of their toxic emissions *as well as the extent and their patterns of use*. Patterns of use, in turn, are related to dependence potential and consumer appeal.") (emphasis added), Exhibit US-113.

[161] H.R. Rep. No. 111-58, Pt. 1 (2009); *see also WHO, The Scientific Basis of Tobacco Product Regulation*, at 26, ("Younger and inexperienced smokers are more inclined to try flavoured cigarettes since enticing flavouring agents suppress the harsh and toxic properties of tobacco smoke, making it more appealing to novices in smoking."), Exhibit US-113.

[162] *EC – Asbestos (AB)*, 122, 128.

[163] It is also worth noting how the Appellate Body in *EC – Asbestos* treated the fact that the measure at issue in the dispute was a technical regulation. Although the Appellate Body reversed the panel's finding and concluded that the measure at issue was in fact a technical regulation, the Appellate Body did not then proceed to conduct a "like

116. The characteristics of cloves noted above are the most relevant, and should be accorded significant weight. And even when one examines other factors, those factor do not support Indonesia's argument that clove cigarettes are like other types of cigarettes. The United States also has noted other differences between clove and other cigarettes: Clove cigarettes contain the harmful chemical, coumarin, which tobacco and menthol cigarettes do not contain.[164] Evidence shows that clove cigarettes involve unique health risks to individual users.[165] Clove cigarettes also tend to contain a different type of tobacco than regular and menthol cigarettes produced in the United States.[166] Clove cigarettes tend to be brown, whereas regular and menthol cigarettes tend to be white. Cloves tend to be sold in different stores than tobacco or menthol cigarettes. In addition, clove cigarettes are treated differently than all "other" cigarettes at the 8-digit level under the U.S. GATT 1994 Schedule.[167] The United States likewise notes that Indonesia treats clove cigarettes differently than all "other" cigarettes at the 8-digit level under the WTO tariff bindings.[168]

117. Accordingly, clove cigarettes are different than tobacco or menthol cigarettes in all of the traditional categories – physical properties, consumer tastes and habits, end-uses, and tariff treatment. To the extent that "likeness" is determined based on an accumulation of factors, the United States considers that these factors should be considered, and taken together, defeat Indonesia's suggestion that clove cigarettes are like tobacco and menthol cigarettes.

4. Less Favorable Treatment

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product" analysis under Article 2.1 of the TBT Agreement (even though Canada had submitted a claim under that provision) because the Appellate Body determined that the record did not contain factual findings sufficient to form a basis for the analysis (para. 78). So, unlike in this case, in *EC – Asbestos* the national treatment analysis was confined solely to the context of the GATT 1994 and the factual record already established. Therefore, the Appellate Body did not reach the question of how the context of the TBT Agreement might affect, or add new dimensions, to the analysis.

[164] Indonesia continues to cite older studies which show that tobacco and menthol cigarettes used to contain coumarin, and selectively ignores more recent studies that show that tobacco and menthol cigarettes no longer tend to contain this chemical. U.S. First Written Submission, para. 166; U.S. Answer to Q34, paras. 77-79. Exhibit US-46, Exhibit US-71, Exhibit US 72.

[165] U.S. Answer to Q38(b), paras. 90-94. *See also WHO, The Scientific Basis of Tobacco Product Regulation*, at 35,("Bidis ... and Kreteks (clove-flavoured tobacco cigarettes, often imported from Indonesia) are alternative tobacco products that have higher concentrations of nicotine, tar, and carbon monoxide than conventional cigarettes. ... Kretek smoking is associated with increased risk for lung damage and abnormal lung function.") Exhibit US-113; Exhibit US-37, Exhibit US-38, Exhibit US-45, Exhibit US-48, Exhibit US-105.

[166] U.S. Answer to Q33, paras. 75-76.

[167] Exhibit US-91.

[168] *See* Schedule XXI – Indonesia, Part I, Most-Favoured-Nation Tariff, Section I, Agricultural Products, Section I, A Tariffs. The United States also notes that the European Union also accords different treatment at the 8-digit level between clove and other cigarettes. *See* Schedule LXXX – European Communities, Part I, Most-Favoured-Nation Tariff, Section I, Agricultural Products, Section I, A Tariffs.

118. The national treatment provisions contained in Articles III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement prohibit measures that accord imported products less favorable treatment than like domestic products. As the United States explained in its answer to question 52 of the Panel's First Set of Questions to the Parties, the treatment at issue in both provisions is the treatment of imported products *compared to* the treatment of like domestic products. In other words, the national treatment obligations fundamentally concern an analysis of the treatment accorded by a measure to products based on the national origin of the products.

a. Indonesia Is Incorrect That Section 907(a)(1)(A) Accords Less Favorable Treatment If *One* Indonesian Import Is Included Among Prohibited Characterizing Flavors and *One* U.S. Produced Cigarette Is Not

119. Indonesia would have the Panel consider the "less favorable treatment" claim without respect to the context of the relevant Agreements and based on an extreme view that has been squarely rejected by the Appellate Body. Indonesia submits that all different types of cigarettes are a single "like product", and that if *any* domestic cigarette is permitted under section 907(a)(1)(A), the measure accords less favorable treatment to Indonesian products.[169] Indonesia bases this view not on the text of the WTO Agreement nor on any findings of the Appellate Body or of a WTO Panel; rather, Indonesia relies on a single GATT Panel report *(US – Malt Beverages)*.[170]

120. As an initial matter, the circumstances in this case are different than the circumstances in *US – Malt Beverage*. *US – Malt Beverages* concerned a range of state measures, several of which provided preferential treatment to small and/or local producers.[171] One of the arguments raised in defense of the measures was that other domestic products, made in other U.S. states, also received the same treatment as imported products under these measures. It was in this context that the panel commented that imports must be accorded treatment no less favorable that *any* domestic product - *i.e.*, the product that the state adopting the measure singled out for favorable treatment. In particular, the panel found the fact that domestic products from other states were accorded the same unfavorable treatment as that accorded imports was not an adequate answer to a national

[169] Indonesia Answer to Q 51, para. 107.

[170] Indonesia Answer to Q51, para. 107 (quoting *US – Malt Beverages (GATT Panel)*, para. 5.17).

[171] *US – Malt Beverages (GATT Panel)*, paras. 5.16-5.17, 5.29-5.37.

treatment claim.[172] No similar situation is present here, where the issue is a federal regulation that accords the same treatment regardless of the state or national origin.

121. In any case, the "best treatment" approach advocated by Indonesia is inconsistent with the language of GATT Article III:4 and Article 2.1 of the TBT Agreement. The relevant comparison is the treatment accorded to imported "products" and like domestic "products" – not single imports and compared to single like domestic products. There is no textual basis to interpret either national treatment provisions as providing for treatment of "an imported product" that is no less favorable than the treatment of "a domestic product."

122. Nor is it consistent with the Article III principle that measures should not be applied so as to afford protection to domestic production and the TBT affirmation that Members may take measures to protect the public health, including by laying down product characteristics. Were Indonesia's view to prevail – and if national treatment obligations were violated when a *single* import is restricted by a measure and a *single* like domestic product is not – Members' ability to regulate for the protection of human health or any other purpose would be seriously encumbered. Any measure that distinguished between products for legitimate reasons – for example to protect public health – could be construed as resulting in national treatment violations.

123. Further, in *EC – Asbestos* the Appellate Body has rejected the "best treatment" approach Indonesia advances. The Appellate Body affirmed that the relevant comparison for purposes of the "less favorable treatment" is not between an import as compared to the "best" treated like domestic product, but rather "a complaining Member must [...] establish that the measure accords to the *group* of 'like' *imported* products 'less favorable treatment' than that it accords to the group of 'like' *domestic* products."[173] In referring to the "group of 'like' *imported* products" and the "group of 'like' *domestic* products," the Appellate Body reflected that the type of distinctions with which Article III:4 is concerned are those that distinguish between products based on wether they are domestic or imported, or said another way, based on origin.[174]

124. In fact, the Appellate Body makes the important observation in *EC – Asbestos* that, to the extent that the term "like product" under Article III:4 of the GATT is broad, it is tempered or hemmed in by the fact that "a Member may draw distinctions between products which have been found to be 'like', without, for this reason alone, according to the group of 'like' *imported*

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[172] *US – Malt Beverages (GATT Panel)*, para. 5.17 ("The Panel did not consider relevant the fact that many of the state provisions in this dispute provide the same treatment to products of other states of the United States as that provided to foreign products. The national treatment provisions require contracting parties to accord imported products treatment no less favourable than that accorded to any like domestic product, whatever the domestic origin."); para. 5.33 ("The Panel recalled the United States argument that the wholesaler requirement in the case of imported beer and wine was non-discriminatory and consistent with Article III:4 because it also applied to out-of-state domestic products.").

[173] *EC – Asbestos (AB)*, para. 100 (emphasis added and in original).

[174] *EC – Asbestos (AB)*, para. 100 (emphasis in original).

products 'less favorable treatment' than that accorded to the group of 'like' *domestic* products."[175] In other words, a measure that accords different treatment to some imported products as compared to some like domestic products based, for example, on their characteristics as trainer cigarettes (and not based on their origin) is not a measure that accords different treatment to "the group of 'like' *imported* products" than the "group of 'like" *domestic* products." It is a measure that accords different treatment to the group of products that are trainer cigarettes than that accorded to the group of products that are not trainer cigarettes. Consistent with the Appellate Body's report in *EC – Asbestos*, distinctions based on criteria other than origin are not distinctions that accord less favorable treatment to the group of imported products as compared to the group of like domestic products.

125. In this case, Indonesia asks the Panel to confine its treatment comparison to clove cigarettes, on one hand, and any domestic cigarette not banned under section 907(a)(1)(A), on the other hand.[176] This approach could entirely undermine Members' right to draw legitimate distinctions between like products without necessarily according less favorable treatment, where an import may be caught by a measure that does not also catch every domestic product. As noted, if countries are to be able to begin to ban categories of cigarettes within their borders – as called for under the FCTC – they must be able to identify and target, based on public health criteria, those cigarettes that appropriately can be banned. Such measures should not be deemed to treat imported products less favorably than domestic products if *any* imported cigarette falls under the ban and not *every* domestic cigarette falls under the ban.

b. Indonesia Has Not Established That Section 907(a)(1)(A) Accords Less Favorable Treatment to Indonesian Cigarettes Compared to Cigarettes Produced in the United States

126. Even apart from its misguided "best treatment" argument, Indonesia has failed to demonstrate that section 907(a)(1)(A) accords less favorable treatment to imported cigarettes.

127. Whether a measure accords less favorable treatment turns on how the measure treats imported products as compared to domestic products. For this purpose, the Appellate Body has examined whether the measure alters the conditions of competition to the detriment of imported products as compared to domestic products – but has made clear that a measure does *not* alter the conditions of competition to the detriment of imported products when the alleged detriment is "explained by factors or circumstances *unrelated to the foreign origin of the product*s."[177] Moreover, "[t]he term 'Less favorable treatment' expresses the principle, in Article III:1, that

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[175] *EC – Asbestos (AB)*, para. 100 (emphasis in original).

[176] Indonesia Answer to Q49, para. 103 ("For purposes of the "less favorable treatment" analysis, the imported product is clove cigarettes and the domestic product(s) would be any type of cigarette not banned by Section 907(a)(1)(A) that the Panel found to be "like" clove cigarettes.).

[177] *DR – Cigarettes (AB)*, para. 96 (emphasis added); *see also Korea – Beef (AB)*, para. 144; *Mexico – Soft Drinks (Panel)*, para. 8.118.

internal regulations 'should not be applied ... so as to afford protection to domestic production."[178] Accordingly, while there is no single approach or necessarily decisive factor in reaching a legal conclusion of "less favorable treatment" – and different factors are significant given particular facts and circumstances – the guiding principle to the analysis is that a measure must not single out imports based on national origin so as to afford protection to domestic product.

128. This also holds with respect to Article 2.1 of th the TBT Agreement, which must be interpreted so as to permit technical regulations based on legitimate product distinctions – even where those distinctions may have a different impact on different products. Indonesia seeks to remove any analytic task by boiling down the "less favorable treatment" analysis to a mechanical question of whether a measure applies to any import and not to any like domestic product. This approach is insufficient. The essence of national treatment obligations is whether a measure accords less favorable treatment to imported products as compared to domestic products, and that question requires an examination of all relevant facts.

129. In this case, the fact that section 907(a)(1)(A) is a public health measure must be considered in examining any allegation of less favorable treatment. As the United States has explained throughout its submissions,[179] section 907(a)(1)(A) is an integral and consistent part of broader legislation designed to combat the difficult public health problem of tobacco use in the United States. Product distinctions based on how consumers use products, and with regard to the consequences that could result from different regulations, are consistent with this public health approach. Section 907(a)(1)(A) is based on how cigarettes are used by the population as a whole, and not based on the relative danger of cigarettes to individual users.[180] Therefore, in this case, the fact that lesser-used cigarettes are banned should not be confused with discrimination against imported products as compared to domestic products. The prohibition on certain flavors is part of a broader regulatory regime to combat smoking. Section 907(a)(1)(A) bans those cigarettes which play a role in facilitating addiction and can appropriately be banned, in light of overall public health considerations. The fact that cloves fall under section 907(a)(1)(A) has nothing to do with their national origin and owes solely to how they are used by consumers in the United States and other public health factors.

130. The only evidence that Indonesia has submitted to demonstrate less favorable treatment is the fact that clove cigarettes are prohibited by the measure, and tobacco and menthol cigarettes are not. This evidence is incomplete and otherwise insufficient to establish less favorable treatment. First, it ignores the fact that section 907(a)(1)(A) affects U.S. produced cigarettes, and does not single out imports generally or Indonesian imports in particular. Second, Indonesia has adduced

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[178] *EC – Asbestos (AB)*, para. 100.

[179] *See*, *e.g.*, U.S. First Written Submission, paras. 103-143.

[180] Indonesia is disingenuous when it suggests that the "sole purpose [of section 907(a)(1)(A)] is to 'affect' the sale, distribution, etc. of clove cigarettes." Indonesia Opening and Closing Statement, para. 53. Again, Indonesia attempts to entirely scrub from the analysis relevant facts, such as the public health basis for the ban, which complicate its mechanical analysis.

no other argument or evidence to demonstrate that any detriment to clove cigarettes is dependent on the foreign origin of the product.

i. Section 907(a)(1)(A) Affects U.S. Produced Cigarettes

131. Indonesia's evidence is incomplete because, at every stage of the national treatment analysis, Indonesia attempts to subtract the relevant fact that section 907(a)(1)(A) *also affects domestic cigarettes*.[181] As the United States has demonstrated, from 1999 until at least 2006, U.S. cigarette manufacturers, in particular R.J. Reynolds, aggressively marketed a new line of flavored products specifically targeted at young people, under the business plan of hooking new cigarette addicts.[182] In 2006, a number of states attorneys general investigated the threat posed by a slew of exotic flavors put on the market by R.J.Reynolds. Based on the investigation, some U.S. states threatened litigation that resulted in the 2006 Consent Agreement, under which R.J. Reynolds agreed to pull the investigated cigarettes off the market in relevant states and to limit its advertising of any new developed flavors to adult-only venues. Around the same time, in 2004, federal legislation, including the language of section 907(a)(1)(A) was proposed.

132. As both parties have recognized, it is difficult to ascertain market data on U.S.-produced characterizing flavors, especially during these years that such flavors were coming under the spotlight and immediately preceding when the ban went into effect.[183] The U.S. Government was not tracking sales or other distribution at the level of this precise type, and is not aware of any such data. Nonetheless, evidence shows that U.S.-produced cigarettes with characterizing flavors were on the market in 2008 and 2009.[184] The United States and Indonesia do not appear to disagree that the 2006 Consent Agreement and looming federal legislation likely influenced the decline of flavored cigarettes on the market in the years immediately leading up to when section 907(a)(1)(A) went into effect. It is likely that there were fewer cigarettes with characterizing flavors on the market immediately before the ban than in the years between 1999 and 2006.

133. More importantly, however, the United States and Indonesia also do not appear to disagree that, but for government intervention, U.S. manufacturers would be selling flavored cigarettes on the U.S. market. Indonesia claims that the 2006 Consent Agreement accounts for the fact that most cigarettes with characterizing flavors were removed from the market before section

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[181] *See, e.g.,* Indonesia Opening and Closing Statement, paras. 46.

[182] U.S. First Written Submission, paras. 43-53.

[183] U.S. Answer to Q17, paras. 41-45. Indonesia Answer to Q17, para. 48.

[184] ACNielsen, Table 1: *Known and Possible "Flavored" Cigarettes Brands Sold in the United States, 2008* and ACNielsen, Table 2: *"Flavored" Clove Brands Sold in the United States in 2008*, Exhibit US-52; Examples of Cigarettes Certified for Sale in the United States as of 2009, Exhibit US-62.

907(a)(1)(A) went into effect.[185] Implicit in this (incorrect) claim is the recognition that cigarettes with characterizing flavors would be on the market unless they are effectively barred. However, as the United States has demonstrated, the 2006 Consent Agreement – although helpful – was insufficient to properly address the threat of cigarettes with characterizing flavors.[186] Federal legislation was critical to remove the threat.

134. Section 907(a)(1)(A) protects consumers from products that, given the chance, would be aggressively marketed and sold in the U.S. market. This threat is real: U.S. cigarette manufacturers have developed characterizing flavors and sought to market them, and have been affected by the ban. Looking at what flavors were on the market in 2009 only captures a small part of the effect of section 907(a)(1)(A) on U.S. products. In assessing the market in *Mexico – Soft Drinks*, the panel considered a time period of roughly five years before the measure.[187] In this case, it is even more important to gauge the impact of the ban by considering the years leading up to it, because of the well-publicized campaign against cigarettes with characterizing flavors that culminated in section 907(a)(1)(A), and the undisputed fact that U.S. producers would sell their products if given the chance.

135. The United States also takes issue with Indonesia's assertion that the market share of U.S. cigarettes with characterizing flavors was not "significant"[188] or "relevant." Indonesia asserts that "virtually all domestic cigarettes *with relevant market shares* were not affected"[189] by section 907(a)(1)(A). However, Indonesia does not specify what it would consider a "relevant market share" with respect to section 907(a)(1)(A) and in comparison to the market share of clove cigarettes in the United States. Section 907(a)(1)(A) applies to a very small percentage of the total of all types and volume of cigarettes sold in the United States. One of the reasons the ban on characterizing flavors other than tobacco or menthol is appropriate for the public health in the United States is that it applies to a relatively small number of cigarettes, which are nonetheless significant from a public health perspective, because they are especially attractive to young people. Clove cigarettes comprised between 0.06% and 0.13% of the U.S. market in the years

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[185] Indonesia First Written Submission, para. 3 (citing the 2006 Consent Agreement for the claim that by the time section 907(a)(1)(A) went into effect, most cigarettes with flavors such as strawberry, grape, orange, chocolate, and cinnamon were already off the market); Indonesia Answer to Q17, para. 48 ("There is no evidence of a significant market share for candy-flavored cigarettes following the 2006 Consent Agreement and the implementation of the ban in 2009.").

[186] U.S. First Written Submission, paras. 93-102 (In particular, the Consent Agreement applies only to a few limited products made by R.J. Reynolds, does not apply to cigarettes made by other companies, and does not entirely remove cigarette with characterizing flavors from the market in *any* state.).

[187] *Mexico – Soft Drinks (Panel)*, paras. 8.119-8.20.

[188] Indonesia Answer to Q17, para. 48.

[189] Indonesia Answer to Q48, para. 102 (emphasis added).

2000-2009,[190] and the share of other flavors on the market, which also was very small, should be considered "relevant" to the extent that the share of clove cigarettes is considered relevant.

136. Accordingly, it is not the case that section 907(a)(1)(A) targets Indonesian cigarettes or imports generally. Both imported and U.S. products are affected by the measure, and in each case, it is products with a relatively small market share. In addition, the vast majority of imported cigarettes are still permitted under the measure. Section 907(a)(1)(A) was adopted based on what is appropriate for the public health.

ii. Indonesia Fails to Establish That Any Detriment to Clove Cigarettes Is Dependent Upon the Foreign Origin of the Product

137. Not only has Indonesia failed to demonstrate that the prohibition in section 907(a)(1)(A) singles out imports, Indonesia also has not demonstrated that any detriment to clove cigarettes is dependent upon the foreign origin of clove cigarettes. As noted above, the fact that cloves fall under section 907(a)(1)(A) has nothing to do with their national origin and owes solely to how clove cigarettes are used by consumers in the United States and other public health factors.

138. As articulated by the Appellate Body in *DR – Cigarettes*, a measure does not alter the conditions of competition to the detriment of imported products when the alleged detriment is "explained by factors or circumstances *unrelated to the foreign origin of the product*, such as the market share of the importer."[191] Here, the Appellate Body re-affirms the fundamental principal that the "treatment" analysis concerns imported products *as compared to* domestic products, and that not all detriments claimed by imports are evidence of less favorable treatment – the detriment must be determined, base on all relevant evidence, to depend on the foreign origin of the product. This principal is reinforced by the context of the TBT Agreement, which recognizes that technical regulations legitimately will "lay down product characteristics" and thus distinguish between products. That such regulations may impose different costs and burdens on different products, does not prove that they accord less favorable treatment to imported products that happen to face costs or burdens that some domestic products may not.

139. The United States disagrees with Indonesia and those third parties that seek to minimize the thrust of the Appellate Body's statement in *Dominican Republic – Cigarettes*. For example, Indonesia quotes Brazil's assertion that the meaning of this statement is simply "that the detrimental effects to imported products are not, *ipso facto*, tantamount to discrimination, as other characteristics of these effects are also pertinent to the evaluation of whether a less favourable treatment has been accorded to imported products."[192] The United States agrees that detrimental

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[190] U.S. Answer to Q16, para. 38.

[191] *DR – Cigarettes (AB)*, para. 96 (emphasis added).

[192] Indonesia Answer to Q52, paras. 110-112 (citing Brazil Oral Statement at the first panel meeting, para. 12-13.).

effects are not, *ipso facto*, tantamount to discrimination. However, neither Indonesia nor Brazil explain what exactly Brazil means by the explanation that "other characteristics of these effects are also pertinent to the evaluation of whether a less favourable treatment has been accorded to imported products." It appears that Brazil simply has replaced the Appellate Body's formulation that the detriment must depend on foreign origin with the formulation that "other characteristics" of the effect on imports "are pertinent." This explanation seems to be presented as a paraphrase, however, that is not self-evident. Neither Indonesia nor Brazil has offered a compelling reason not to accord the ordinary meaning to the Appellate Body's plain words: a detriment does not necessarily evince less favorable treatment when it is explained by factors or circumstances *unrelated to the foreign origin of the product*. Whether a detriment is explained by the foreign origin of the product is essential to the "treatment analysis."[193]

140. The panel in *EC – Biotech* affirms the point. The panel determined that Argentina failed to properly allege "less favorable treatment" because it was not self-evident that the "alleged less favorable treatment of imported biotech products is explained by the *foreign origin of these products*, rather than, for instance, *a perceived difference* between biotech and non-biotech products *in terms of their safety*, etc."[194] The Panel reasoned further that "Argentina has not adduced evidence sufficient to raise a presumption that the alleged less favorable treatment is explained by the foreign origin of the relevant biotech products."[195] In other words, in *EC – Biotech*, Argentina's allegation that imported biotech products were not allowed to be marketed, while corresponding non-biotech products were allowed to be marketed, was an insufficient basis – in itself – to raise a presumption of less favorable treatment. Argentina needed to adduce evidence that the alleged different treatment was based on the origin of the products. Even if it were true – which it is not – that section 907(a)(1)(A) bans only Indonesian imported cigarettes while permitting domestic cigarettes, such an allegation, in itself, does not raise the presumption that this difference is based on origin and thus accords less favorable treatment.

141. The United States should reiterate here that a "less favorable treatment" determination is not simply a matter of applying a single "test;" it is a fact intensive inquiry, in which different factors may be relevant in different circumstances. Ultimately, however, the analysis concerns whether a measure discriminates against imported products based on their national origin.

142. The United States also notes here that we are not suggesting that the "subjective intent" of a measure is a determining factor as to whether a measure discriminates between imported and domestic products.[196] However, consistent with the Appellate Body approach in previous Article

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[193] *EC – Biotech*, para. 7.2514 (finding that Argentina failed to properly allege less favorable treatment where it was not self-evident that the treatment was explained by the foreign origin of the products rather than a perceived difference between biotech and non-biotech products in terms of their safety.).

[194] *EC – Biotech*, para. 7.2514 (emphasis added).

[195] *EC – Biotech*, para. 7.2514.

[196] Indonesia Opening and Closing Statement, paras. 27, 31-32.

III disputes, it *is* relevant to conduct a "comprehensive and objective analysis of the structure and application of the measure in question on domestic as compared to imported products" to determine whether the objective of the measure is to afford protection to domestic production or fulfil some other legitimate objective.[197] In addition, "although it is true that the aim of a measure may not easily be ascertained, nevertheless its protective application can most often be discerned from the *design*, the *architecture*, and the revealing *structure* of a measure."[198]

143. In this case evidence shows that the design, architecture, and structure of section 907(a)(1)(A) are consistent with an acceptable public health approach to regulating cigarettes.[199] Section 907(a)(1)(A) is designed to prohibit types of cigarettes that are especially appealing to young people, but not heavily used by adults. The fact that tobacco and menthol flavored cigarettes are not banned under section 907(a)(1)(A) is not an "anomaly" in the design, structure and operation of the measure. Tobacco and menthol cigarettes are the most heavily smoked cigarettes by adults in the United States, and that is why they are not banned, regardless of where they are produced. The FCTC confirms the legitimacy of this approach in its Partial Guidelines to Articles 9 and 10, where it states that countries should "aim to implement the most *effective* measures that they can *achieve."*[200] Consistent with this approach, the Tobacco Control Act establishes product standards, including section 907(a)(1)(A), based on what is appropriate for the public health.

144. Indonesia has failed to establish that the product distinctions under section 907(a)(1)(A) are in any way based upon the origin of the regulated products, either in law or in fact. Indonesia's key claim – that the flavor prohibition in section 907(a)(1)(A) targets Indonesian cigarettes – is only maintained by ignoring the relevant fact that the section 907(a)(1)(A) flavor prohibition applies to U.S. produced cigarettes as well (and does not apply to the vast majority if imports). Moreover, this simple ratio is not necessarily dispositive of less favorable treatment. The analysis must

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[197] *Japan – Alcoholic Beverages (AB)*, p. 26-27 (establishing the difference between an analysis of subjective intent and of the objective intent as manifested in the measure itself); *see also Chile – Alcoholic Beverages (AB)*, paras. 59-63. It should be noted that it is Indonesia, and not the United States, that suggests incorrectly that the "intentions inhabiting the minds of individual legislators or regulators ... bear upon the inquiry" in this dispute. *See*, *e.g.*, Indonesia's First Written Submission, paras. 24-27; Indonesia's Opening and Closing Statement, para. 86 (citing legislators' statements as evidence of the purpose behind section 907(a)(1)(A)). The Appellate body rejected the notion that the subjective intent of legislators should be a basis for determining the objective of a measure in *Chile - Alcohol. Chile – Alcoholic Beverages (AB)*, para. 62.

[198] *Chile – Alcoholic Beverages (AB)*, para. 62 (emphasis in original) (citing *Japan – Alcoholic Beverages*, para. 29). The United States notes that this analysis arises in the context of the second sentence of Article III:2, where the Appellate Body has recognized that whether a measure is "applied so as to afford protection to domestic production" is a distinct element in establishing a claim under that provisions. It is not a distinct element under Article III:4. Nevertheless, Article III:1 establishes that whether a measures is applied so as to afford protection to domestic production is a fundamental principle of Article III, including Article III:4, and thus the analysis is relevant evidence, even if it does not constitute a distinct element.

[199] U.S. First Written Submission, paras. 209-211; U.S. Answer to Q19, paras. 49-54.

[200] Partial Guidelines to Articles 9 and 10 of the FCTC, FCTC/COP/4/DIV/6, section 3.1.2, p. 52 (emphasis added).

consider *all* relevant facts. In this case, the facts do not support a finding of *de jure* or *de facto* less favorable treatment. In this case, the facts, taken together, show that section 907(a)(1)(A) lays out product characteristics that have nothing to do with the origin of products, and therefore do not accord imported cigarettes including Indonesian cigarettes less favorable treatment than like domestic products.

B. Indonesia Has Failed to Establish that Section 907(a)(1)(A) Is Inconsistent with TBT Article 2.2

145. To prove a breach of Article 2.2 of the TBT Agreement, a complaining party must establish that the measure at issue is "more trade-restrictive than necessary to fulfil a legitimate objective." As reviewed in the U.S. First Written Submission, interpreting Article 2.2 in accordance with customary rules of interpretation of public international law, a measure is "more trade-restrictive than necessary to fulfill a legitimate objective" if: (1) there is a reasonably available alternative measure; (2) that fulfills the objective of the measure at the level that the Member imposing the measure considers appropriate; and (3) is significantly less trade restrictive. As elaborated previously and below, Indonesia has not established that such an alternative measure exists, nor could it.[201] Indonesia also puts forth an interpretation of Article 2.2 that is inconsistent with customary rules of treaty interpretation reflected in the *Vienna Convention on the Law of Treaties* ("Vienna Convention"), and accordingly should not be followed.

1. Section 907(a)(1)(A) Is To Fulfill A Legitimate Objective

146. As stated previously, the objective of section 907(a)(1)(A) is protecting public health by reducing smoking prevalence among young people while avoiding the potential negative consequences associated with banning products to which tens of millions of adults are addicted. These negative consequences are the potential consequences for the individual, the U.S. health care system, and the society at large through an expansion of an already existing black market as elaborated in the U.S. First Written Submission.[202] The objective of section 907(a)(1)(A) is legitimate for all the reasons discussed in the U.S. First Written Submission.[203]

147. Further, the level at which the United States considers is appropriate to protect public health is to eliminate from the market, not simply restrict access to, those products that are disproportionately used by young people, but not to eliminate from the market those products to which tens of millions of adults are addicted, and whose precipitous withdrawal from the market may cause negative consequences. This level is reflected in section 907(a)(1)(A). Members are

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[201] U.S. First Written Submission, paras. 270-271.

[202] U.S. First Written Submission, section III.C; U.S. Second Written Submission, section II.B.2.

[203] *See* U.S. First Written Submission, paras. 229-238.

entitled to choose for themselves "which policy objectives they wish to pursue and the levels at which they wish to pursue them."[204]

148. The means by which section 907(a)(1)(A) fulfils its legitimate objective is to ban products that are disproportionately used by young people while not banning products to which tens of millions of adults are addicted.[205] Specifically, in only prohibiting those products that serve as "trainer" cigarettes for young smokers and which are not regularly used by adult smokers, namely cigarettes with characterizing flavors that appeal to young people, while not prohibiting those products to which tens of millions of adults are addicted, namely menthol and tobacco cigarettes, section 907(a)(1)(A) fulfills its objective to reduce youth smoking while avoiding the potential for negative public health consequences that might be associated with banning cigarettes to which tens of millions of adults are addicted.[206]

2. Indonesia's Arguments That Section 907(a)(1)(A) Is Inconsistent with Article 2.2 Are Unfounded

149. Indonesia appears to hinge its Article 2.2 claim on the allegation that section 907(a)(1)(A) does not fulfill its legitimate objective, and has only referenced ever briefly the potential existence of any alternative measures. As such, the United States considers that Indonesia has thus far not even attempted to establish a *prima facie* case, much less established one.[207]

a. Indonesia Has the Burden to Prove Its *Prima Facie* Case

150. As the United States has discussed previously, it is undisputable that Indonesia has the burden of establishing each element of a *prima facie* case.[208] This *prima facie* case must include adducing sufficient evidence that a reasonably available alternative measure exists that is significantly less trade-restrictive and fulfills the objective of the measure at the level that the United States considers appropriate. Yet Indonesia has stated in writing that it is uncertain as to

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[204] *EC – Sardines (Panel)*, para. 7.120. Although it is Members who decide which policy objectives to pursue and at what level to pursue them, where the stated objective of a measure is challenged, a Panel should confirm whether or not a measure's objective is what the responding party asserts it is.

[205] *See* Exhibit US-53; U.S. First Written Submission, paras. 240-243; 31-34.

[206] As noted previously, it is estimated that there are approximately 46 U.S. million adult smokers, 17 million of whom smoke menthol cigarettes. *See also* U.S. First Written Submission, paras. 54-55 (summarizing the survey data as reflected in Exhibit US-53).

[207] U.S. First Written Submission, paras. 270-271.

[208] U.S. First Written Submission, para. 271; U.S. Answer to Q12(d), para. 23.

whether it has the burden of proof on this issue.[209] In any event, and as discussed below, Indonesia has not adduced any evidence that such a measure exists.

151. The United States would further note, however, that Indonesia's burden of proof does not stop there but includes the burden of proving the other elements of its claim. For example, and as discussed further below, Indonesia appears to argue that section 907(a)(1)(A) does not fulfill its legitimate objective, an argument for which it relies on certain on allegations regarding clove use in the United States.[210] Yet, Indonesia appears at times to contend that it is the United States – and not Indonesia – that has the burden for proving the prevalence of clove cigarettess across different age group.[211]

152. Another example concerns the objective of section 907(a)(1)(A). Indonesia asserts the objective is simply reducing youth smoking and ignores that section 907(a)(1)(A) also includes avoiding the potential negative consequences of banning cigarettes to which tens of millions of adults are addicted. Again, to be clear, the United States considers that Indonesia has the burden for each element of its claim.[212]

b. Indonesia Mischaracterizes the Legitimate Objective of Section 907(a)(1)(A)

153. Indonesia repeatedly mischaracterizes the objective of section 907(a)(1)(A) as "reducing youth smoking."[213] That is a gross oversimplification of the objective of section 907(a)(1)(A), which strikes a balance of different public health considerations deriving from the use of different classes of products. Indonesia states that it deduces its view of the objective from the HR Report describing the Tobacco Control Act as a whole.[214] However, Indonesia's view is not supported by

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[209] *See* Indonesia Question to the EU ("After listening to your presentation of the EU's views on TBT Article 2.2, I am *somewhat at a loss as to what the burden of proof is* with respect to what Indonesia must show in terms of the availability of less trade restrictive measures. In particular, I would ask the EU to comment on the extent to which Indonesia may need to show, as part of its *prima facie* case, that a less trade restrictive alternative measure is available to the respondent government.") (emphasis added).

[210] *See, e.g.*, Indonesia First Written Submission, paras. 92-96.

[211] Indonesia is inconsistent on this point. Indonesia seems to take the position that it need only rebut the U.S. position to establish that section 907(a)(1)(A) fails to fulfil a legitimate objective, while at other times Indonesia appears to recognize that it has the burden to establish its assertion. *Compare* Indonesia Answer to Q12(d), para. 42 ("But in order to establish a presumption that it is not necessary to ban clove cigarettes to reduce youth smoking, Indonesia believes it is sufficient to show that there is no evidence to support the claim asserted by the United States that clove cigarettes are popular with youth."), *with* Indonesia Answer to Q18, para. 51 ("If clove cigarettes are not more dangerous and are not widely smoked by youth, Indonesia submits it cannot be necessary to ban them if it was not necessary to ban menthol- and tobacco-flavoured cigarettes.").

[212] *See, e.g.*, Indonesia First Written Submission, paras. 92-96; Indonesia Answer to Q61, para. 129.

[213] *See, e.g.*, Indonesia Answer to Q54, para. 114.

[214] *See, e.g.*, Indonesia Answer to Q54, para. 114.

a fair reading of the House of Representatives Report ("HR Report") nor of the Tobacco Control Act.

154. In determining the objective of a measure, the Appellate Body has indicated that panels should focus on the text, design, architecture, and revealing structure of the measure.[215] The text, design, architecture, and revealing structure of section 907(a)(1)(B) draws distinctions between products, banning some, and allowing others to continue to be produced and sold in the United States. The text thus represents a counter-balancing of interests, which is entirely consistent with theories of sound public health policy making in general and smoking prevention measures in particular.[216] The legislative history of section 907(a)(1)(B) confirms this complex balancing of interests, a point that Indonesia ignores in its analysis. As noted in the U.S. First Written Submission, the HR Report states that the measure is intended to "prohibit the manufacture and sale of cigarettes with certain 'characterizing flavors' that appeal to youth."[217] The HR Report goes on to state that a variety of:

> factors – irregular, experimental, and social setting use and low overall use within the U.S. population – support the Committee's conclusion that precipitous removal of these products from the market will not result in a large number of heavily addicted smokers facing the sudden withdrawal of the products to which they are addicted, with unknown consequences for the health of the individual users or the overall population. The Committee notes that prohibition of a product that is used regularly by a large number of heavily addicted adult users would pose different questions of public health than those posed by the ban in section 907(a)(1). For example, the health care system might not be capable of handling the sudden increased demand for cessation assistance in the case of a more broadly used product, leaving millions of smokers without medical support. In addition, the sudden removal of a legal source for such a product without the type of consideration and review that FDA will be able to conduct might unnecessarily increase the illegal black market risk, which could also pose a health hazard to users.[218]

155. Indonesia is thus in error when it ignores this complex consideration of various factors when characterizing that the objective of section 907(a)(1)(A) is merely to "reduce youth smoking." The reality is far more complex, and the text of the challenged measure, and its underlying objective, reflects this complex reality.

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[215] *Chile – Alcohol (AB)*, para. 62; *see also Japan – Alcohol (AB)*, at 29 ("In conducting this inquiry, panels should give full consideration to all the relevant facts and all the relevant circumstances in any given case.").

[216] *See* U.S. Second Written Submission, section II.A (noting that section 907 provides for a number of factors regarding a product standard that resulted in a ban on clove and other flavors, but that did not result in a ban on all cigarettes).

[217] HR Rep't, at 37, Exhibit US-67; *see also* U.S. First Written Submission, para. 234 (quoting same).

[218] HR Rep't, at 38, Exhibit US-67; *see also* U.S. First Written Submission, para. 236 (quoting same).

c. Indonesia's Argument Regarding Whether Section 907(a)(1)(A) Fulfills Its Legitimate Objective Is Unfounded

156. Indonesia also appears to argue that section 907(a)(1)(A) does not fulfill its objective in that it does not "reduce youth smoking" *enough*, given that the measure does not also ban menthol and tobacco flavored cigarettes, the two most popular types of cigarettes with all age groups, including those people within the age of initiation.[219] Indonesia further argues that it is "legally irrelevant" how the United States treats domestic products, which in its view are "beside the point."[220]

157. Starting with the latter position, it is difficult to understand how the treatment of domestic products is irrelevant to whether section 907(a)(1)(A) fulfils its objective. Rather, whether a measure fulfills its objective at the level the Member considers appropriate, in this dispute, involves evaluating whether in banning a class of cigarettes that are particularly appealing to youth and to which tens of millions of adults are not addicted, section 907(a)(1)(A) fulfils its objective. This evaluation cannot be done by looking at only a portion of the class of cigarettes that section 907(a)(1)(A) bans. Section 907(a)(1)(A) eliminates all cigarettes with characterizing flavors other than menthol and tobacco.

158. With regard to the former, the United States has discussed in detail in both this and previous submissions that nothing in the WTO Agreements limits the United States – or any Member – to pursuing on only those public health measures that *eliminate* the risk they target. Indeed, the preamble to the TBT Agreement makes clear that no Member should not "be prevented from taking measures . . . for the protection of human . . . life or health . . . at the levels it considers appropriate."

159. Further, Indonesia cannot establish that section 907(a)(1)(A) is more trade-restrictive than necessary to fulfill its objective by arguing that section 907(a)(1)(A) should make a greater contribution to its objective. Indonesia must show that whatever contribution section 907(a)(1)(A) makes to its objectives it is more trade-restrictive than necessary because there is a reasonably available alternative measure that fulfils section 907(a)(1)(A)'s objectives that is significantly less

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[219] *See, e.g.*, Indonesia Answer to Q54, para. 115 ("But even if clove cigarettes are popular with a small portion of youth, it does not necessarily follow that Section 907(a)(1)(A) is "necessary" and thus consistent with Article 2.2 of the TBT Agreement. In assessing the question of the necessity of the measure, the Panel would have to consider what contribution Section 907(a)(1)(A) could possibly make toward reducing youth smoking when menthol and regular cigarettes are not banned."); Indonesia Answer to Q12(a), para. 37 ("Indonesia believes that with respect to the question of whether it is 'necessary' to ban clove cigarettes, the most relevant comparison is the rate of clove use by youth to the rate of use by youth of cigarettes exempted from the ban (menthol and tobacco-flavored cigarettes). If it is not 'necessary' ban the cigarettes most popular with youth, it can not be 'necessary' to ban those much less widely used by youth.").

[220] Indonesia Opening Statement, para. 140; *see also* Indonesia Answer to Q62, para. 130 ("An analysis of this question is not relevant to Indonesia's claims given that candy-flavored cigarettes are domestically produced and, thus, a ban on them is not trade-restrictive.").

trade-restrictive. Only if a reasonably available alternative measure is available that (i) fulfils the objective of the measure and (ii) is significantly less trade restrictive can it be concluded that the measure is more trade restrictive than necessary to fulfil its objective. Indonesia has not made, and cannot make, such a showing.

160. The objective of section 907(a)(1)(A) is to protect public health by reducing smoking prevalence among young people while avoiding the potential negative consequences associated with banning products to which tens of millions of adults are addicted. The means by which section 907(a)(1)(A) does this is to ban products that are disproportionately used by young people while not banning products to which tens of millions of adults are addicted. In other words, section 907(a)(1)(A) does not seek to eliminate smoking among young people, but rather to reduce smoking prevalence rates by eliminating a type of product from the market that presents a particular health concern.

161. While one might hypothesize that the United States could have designed a measure that sought to eliminate or reduce smoking among young people to a greater degree than section 907(a)(1)(A), this hypothetical would not advance Indonesia's Article 2.2 claim. Nothing in the TBT Agreement requires Members to seek to fulfill their legitimate objectives to the maximum extent possible, nor at any particular level. To the contrary, as confirmed by the preamble to the TBT Agreement, Members are permitted to fulfill their objectives at the level they consider appropriate.

162. Moreover, a measure more restrictive than section 907(a)(1)(A) would not reflect the broader and more complex objective of section 907(a)(1)(A), which includes avoiding the potential negative consequences associated with banning products to which tens of millions of adults are psychologically and chemically addicted. Indeed, taking into account considerations other than one single objective – for example, taking account of a measure's impact on individuals who may not be the specific target of the measure or costs involved – is consistent with good regulatory practice.[221]

163. Finally, Indonesia also appears to contend that section 907(a)(1)(A) does not fulfill its objective because the United States has not provided any evidence that smoking rates have declined since the ban on September 22, 2009.[222] Indonesia misunderstands both the proper legal inquiry, and the applicable rules for burden of proof. On the proper legal inquiry, Article 2.2 permits Member to adopt technical regulations that are designed "to fulfil a legitimate objective"; Article 2.2 does not impose a requirement that the adopting Member have evidence that the measure has succeeded in fulfilling that objective. With regard to the burden of proof, it is

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[221] For example, the OECD explicitly encourages regulators within different countries to "estimate the total expected costs and benefits of each regulatory proposal." OECD, OECD Reference Checklist for Regulatory Decision-Making, adopted 5 March 1995, available at <www.oecd.org/dataoecd/20/10/35220214.pdf>.

[222] Indonesia Opening Statement, para. 150 ("The United States has failed to provide any evidence that in the 14 months since the ban went into effect, youth smoking rates in the U.S. have fallen at all, much less significantly.").

Indonesia's burden to prove what it asserts is true – in this instance, that section 907(a)(1)(A) does not fulfil its objective. Indonesia has not fulfilled that burden.[223]

d. Indonesia Has Not Adduced Any Evidence That Section 907(a)(1)(A) Is More Trade-Restrictive Than Necessary

164. Indonesia continues to make vague references to "dozens" of different measures that apply to all cigarettes, such as advertising restrictions and the like.[224] Indonesia does not adduce any evidence that any of these measures fulfill the legitimate objective at the level the United States considers appropriate. It has, therefore, not met its burden of establishing a *prima facie* case that section 907(a)(1)(A) is more trade-restrictive than necessary to fulfil its objective.

165. Further, the alternative measures Indonesia identifies would not in fact fulfil the objectives of section 907(a)(1)(A) at the level the United States considers appropriate: those alternatives would all continue to allow trainer cigarettes with characterizing flavors of candy, fruit, liquor, etc. to remain on the market. The United States already imposes significant restrictions on the advertising, marketing, and sale of cigarettes. However, as Congress found that "[b]ecause past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed."[225] Viewed another way, section 907(a)(1)(A) together with other restrictions on the advertising, marketing and sale of cigarettes in place in the United States form part of a comprehensive U.S. strategy to address the public health concerns associated with smoking. If the United States substituted one aspect of this comprehensive strategy for another – for example to forgo section 907(a)(1)(A) in lieu of restrictions already in place in the United States – this would reduce the overall ability of the United States to address the very serious public health concerns associates with smoking. Any measure that does not eliminate from the market cigarettes with characterizing flavors of candy, fruit, liquor, etc. that tens of millions of adults do not smoke does not fulfill the legitimate objective at the level the United States considers appropriate.[226]

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[223] *See US – Wool Shirts and Blouses (AB)*, p. 14 (stating that the party who asserts a fact is responsible for providing proof thereof; the burden of proof rests upon the party who asserts the affirmative of a particular claim or defense; if that party adduces sufficient evidence to raise a presumption that what it claimed is true, then the burden shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption.).

[224] Indonesia Answer to Q57, para. 117; *see also* Indonesia First Written Submission, paras. 106-111.

[225] Tobacco Control Act, sec. 2, finding 6, Exhibit US-7; *see also id.*, finding 15: "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use." *See also* U.S. First Written Submission, para. 252.

[226] The United States would note that the challenged measure is not very trade restrictive in that affects very few imports of cigarettes. As shown in Exhibit US-100, cloves consist of a very small proportion of total cigarettes imported, averaging 5.3% of total imports during the last 10 years in terms of value. As noted previously, cigarette imports are only off a million dollars – less than 1% from the year before. *See* U.S. Answer to Q16, para. 37-40 (discussing Exhibit US-100).

e. None of the Alternative Measures That Would Eliminate Trainer Cigarettes Are Measures That Would Fulfil Section 907(a)(1)(A)'s Objective and Be Less Trade-Restrictive

166. Indonesia has implicitly suggested, although not formally identified, three alternative measures that would eliminate trainer cigarettes with characterizing flavors of candy, fruit, liquor, etc.:

(1) a measure that bans all cigarettes;[227]

(2) a measure that bans all cigarettes except those with a characterizing flavor of tobacco (*i.e.*, menthol, clove and other flavors would be banned);[228] and

(3) a measure that bans all cigarettes except those with characterizing flavors of tobacco, menthol, and clove.[229]

167. Each alternative measure is flawed, however, and none of them establish that section 907(a)(1)(A) is more trade-restrictive than necessary. The United States will analyze the first two alternative measures together as they largely share the same flaws, and the third alternative measure subsequently.

i. Alternative Measures #1 and #2

168. Neither of these first two alternative measures are less trade-restrictive than section 907(a)(1)(A), much less "significantly" so. Alternative measure #2 would be more trade restrictive because it banned more imports – namely all imported menthol cigarettes (in addition to clove and other flavors) – the exact increase in trade restrictiveness is difficult to determine because menthol-flavored cigarettes are classified with tobacco-flavored cigarettes. Alternative measure #1 would also be more trade restrictive, and measurably so – eliminating hundreds of millions of dollars of annual imports.[230] This point is sufficient in of itself to establish that these possible alternative

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[227] *See* Indonesia Answer to Q12(b), para. 39 ("In order to prove claims under Article 2.2 of the TBT Agreement, Indonesia has shown that it is not necessary to ban clove cigarettes in order to reduce youth smoking if menthol and tobacco-flavored cigarettes are not banned . . .").

[228] *See* Indonesia Answer to Q62, para. 130 ("However, so long as menthol, the most popular flavour with youth, is not banned, it is difficult to imagine how a ban on any other flavour, especially products not even on the market at the time the measure was adopted, could be considered "necessary.'").

[229] *See* Indonesia Answer to Q18, para. 51 ("If clove cigarettes are not more dangerous and are not widely smoked by youth, Indonesia submits it cannot be necessary to ban them if it was not necessary to ban menthol- and tobacco-flavoured cigarettes.").

[230] Exhibit US-100 (reflecting that annual cigarette imports to the United States – excluding clove cigarette imports – ranged in value from 164 million to 302 million).

measures are *not* reasonably available alternative measures that are significantly *less* trade-restrictive that fulfil the objective of section 907(a)(1)(A).[231]

169. Second, neither measure fulfills the objective of section 907(a)(1)(A). In particular, while they eliminate trainer cigarettes from the market, they would also eliminate from the market cigarettes to which tens of millions of adults are addicted. They would therefore fail to fulfil a critical component of the objective of section 907(a)(1)(A), specifically avoiding the potential negative health consequences associated with banning cigarettes to which tens of millions of adults are addicted. In other words, alternatives #1 and #2 overshoot the mark in that they would eliminate from the market cigarettes to which tens of millions of adults are addicted and in doing so could lead to the specific negative consequences that section 907(a)(1)(A) seeks to avoid, and thus would not fulfill the objective of section 907(a)(1)(A).

170. For both these reasons, neither alternative measure #1 or #2 constitutes a reasonably available alternative measures that fulfill the objectives of section 907(a)(1)(A) and are significantly less trade-restrictive and therefore are not alternatives that establish that section 907(a)(1)(A) is more trade-restrictive than necessary.[232]

ii. Alternative Measure #3

171. Indonesia also makes reference to a third possible alternative measure: all cigarettes are banned unless they have a characterizing flavor of tobacco, menthol, or clove. This alternative measure does not fulfill the objective of section 907(a)(1)(A).

172. As reviewed above and previous U.S. submissions, the objective of section 907(a)(1)(A) is protecting public health by reducing smoking prevalence among young people while avoiding the potential negative consequences associated with banning products to which tens of millions of adults are addicted. The level at which the United States considers appropriate to protect public health, and that is reflected in 907(a)(1)(A), is to eliminate from the market those products that are disproportionately used by young people but not to eliminate from the market those products to

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[231] In this regard, Indonesia's answer to the Panel's Question 53 is incorrect. *See* Indonesia Answer to Q53, para. 113 ("Whether extending the ban on clove cigarettes to include menthol cigarettes could remedy a violation of Article 2.2 of the TBT Agreement would depend in part on whether it was accompanied by sufficient scientific evidence that doing so is "necessary to fulfil a legitimate objective."). The existence of such a measure could never prove that section 907(a)(1)(A) is more trade restrictive than necessary regardless of what the science shows as the measure is not less trade restrictive.

[232] Finally, the United States would note that bans all cigarettes with characterizing flavors except tobacco to be incoherent in the context of Indonesia's argument. That is to say, in Indonesia's view, section 907(a)(1)(A) is inconsistent with Article 2.2 because it bans less "popular" types and not the more "popular" class of menthols. However, it is uncontested that the most "popular"class of cigarettes regardless of age range is tobacco-flavored cigarettes. Accordingly, the United State does not understand how, in Indonesia's view, such a measure could be consistent with the obligation given that the most "popular" class of cigarettes would remain on the market.

which tens of millions of adults are addicted.[233] Alternative #3 would not eliminate from the market those products that are disproportionately used by young people; rather it would leave a portion of products that are disproportionately used by young people on the market (*i.e.*, clove cigarettes). Alternative #3 would therefore not fulfil the objective of section 907(a)(1)(A).

173. As no other alternative measure would appear to exist, section 907(a)(1)(A) cannot be considered to restrict trade more than is necessary to fulfil its legitimate objective and therefore is not inconsistent with TBT Article 2.2.

3. TBT Article 2.2 Should Be Interpreted in Accordance with Articles 31 and 32 of the Vienna Convention

174. Indonesia contends that, given the "similarity of the text of Article XX of the GATT 1994 and its subparagraph (b) and Article 2.2 of the TBT Agreement and its Preamble," the Panel must look at the panel and Appellate Body reports that considered GATT Article XX to understand what TBT Article 2.2 obliges of Members.[234] Thus, the question that Indonesia believes must be answered, is not the one asked by Article 2.2, but the one asked by Article XX(b) – whether it is "necessary" for the United States to take the measure it did.[235] The EU further contends that the Panel cannot stop its analysis there, however, but must continue and determine whether the measure is inconsistent with the chapeau of GATT Article XX to consider whether the Member has acted consistently with TBT Article 2.2.[236]

175. Neither of these arguments are in accordance with the Vienna Convention, and both should be rejected.

a. There Is No Basis to Apply the Interpretation of GATT Article XX(b) to the Interpretation of TBT Article 2.2

176. Articles 31 and 32 of Vienna Convention provide that the terms of a treaty shall be interpreted based on their ordinary meaning in their context in light of the treaty's object and

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[233] U.S. Answer to Q58(b), para. 135.

[234] *See* Indonesia Answer to Q58(a), para. 119; Indonesia First Written Submission, paras. 77, 86-89; *see also* Brazil Third Party Submission, para. 33 ("Brazil sees the past rulings on Article XX of GATT 1994 as highly relevant to the clarification of the obligation in Article 2.2 of the TBT Agreement.").

[235] *See, e.g.*, Indonesia Answer to Q12(b), para. 39 ("In order to prove claims under Article 2.2 of the TBT Agreement, Indonesia has shown that it is not necessary to ban clove cigarettes in order to reduce youth smoking if menthol and tobacco-flavored cigarettes are not banned and that there would have been minimal risk to the purpose of the FSPTCA if clove had not been included in the ban on flavoured cigarettes."); Indonesia Answer to Q12(a), para. 37 ("Indonesia believes that with respect to the question of whether it is "necessary" to ban clove cigarettes, the most relevant comparison is the rate of clove use by youth to the rate of use by youth of cigarettes exempted from the ban (menthol and tobacco-flavored cigarettes). If it is not "necessary" ban the cigarettes most popular with youth, it can not be "necessary" to ban those much less widely used by youth.").

[236] EU Answer to Q2, para. 8.

purpose and that recourse may be had to certain supplementary means of interpretation to confirm the meaning of terms resulting from application of Article 31. As elaborated in the U.S. First Written Submission, based on the ordinary meaning of its terms, a measure that is more trade-restrictive than necessary is one that restricts trade more than is needed or required to fulfill the measure's legitimate objective, or stated another way, that there is another measure that could fulfill the measure's legitimate objective but that restricts trade less.[237]

177. Further, the preamble to the TBT Agreement provides that no Members should be prevented from taking measures necessary *inter alia* to protect human life or health at the level the Member considers appropriate, and the text of the TBT Agreement makes clear, for example in Articles 1.6, 2.9 and 5.6, that it is not concerned with measures that have only an insignificant affect on trade. Together, Article 2.2 read based on the ordinary meaning of its terms in its context in the TBT Agreement, and in light of the agreement's object and purpose, supports that a measure is more trade-restrictive than necessary to fulfill a legitimate objective when a reasonably available alternative measure exists that would fulfill the Member's objective at the level the Member considers appropriate and is significantly less trade-restrictive.

178. Further relevant context supporting this interpretation of Article 2.2 is Article 5.6 of the *Agreement on Sanitary and Phytosanitary Measures* ("SPS Agreement"). Given the textual similarities between SPS Article 5.6 and TBT Article 2.2, as well as the similarities between the TBT and SPS Agreements themselves,[238] it makes sense to interpret Article 2.2 of the TBT Agreement similarly to Article 5.6 of the SPS Agreement.[239] The letter from the Director-General of the GATT cited in the U.S. First Written Submission[240] as supplemental means of interpretation under Article 32 of the Vienna Convention further confirms that TBT Article 2.2 should be interpreted similarly to SPS Article 5.6, specifically that a measure cannot be considered more trade-restrictive than necessary in the absences of a reasonably available alternative measure that is significantly less-trade restrictive.

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[237] U.S. First Written Submission, paras. 259-265.

[238] Article 5.6 of the SPS Agreement requires a Member to ensure that its SPS measures are "not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection" while Article 2.2 of the TBT Agreement prohibits measures that are "more trade-restrictive than necessary to fulfill a legitimate objective." The Appellate Body has also noted the similarities between the SPS and TBT Agreements. *EC – Sardines (AB)*, para. 274.

[239] Indonesia claims that recognizing SPS Article 5.6 is relevant context for TBT Article 2.2 as part of a Vienna Convention analysis would be a "breathtaking rewrite of the TBT Agreement." Indonesia Opening and Closing Statement, para. 155. The United States would note that while Article 2.2 of the TBT Agreement and Article 5.6 of the SPS Agreement use slightly different language (for example "not be more trade-restrictive than necessary" versus "are not more trade-restrictive than required") the language in Article 5.6 of the SPS Agreement is much more similar to the language in Article 5.6 of the SPS Agreement than Article XX of the GATT 1994. In addition, as even the EU points out, the two provisions play similar "role[s]" in their respective agreements. EU Opening Statement, para. 21 ("Certainly, the role played by Article 5.6 of the SPS Agreement in the operation of the agreement is similar to that of Article 2.2 of the TBT Agreement.").

[240] U.S. First Written Submission, n.306.

179. Taken together, the text of Article 2.2 in its context and in light of the object and purpose of the TBT Agreement, means that a measure is "more trade-restrictive than necessary to fulfill a legitimate objective" if there is a reasonably available alternative measure that fulfills the measure's objectives that is significantly less trade-restrictive. Accordingly, to prove that the challenged measure is inconsistent with Article 2.2 of the TBT Agreement, Indonesia must establish that: (1) there is a reasonably available alternative measure; (2) that measure fulfills the objectives of the U.S. provisions at the level that the United States has determined is appropriate; and (3) is significantly less trade-restrictive.

180. Rather than applying an interpretation of Article 2.2 based on Articles 31 and 32 of the Vienna Convention, Indonesia instead adopts an interpretation of Article 2.2 of the TBT Agreement based on prior panels' and the Appellate Body's interpretation of Article XX of the GATT 1994.[241] As discussed in the U.S. First Written Submission, it would not be appropriate to apply the same interpretive approach panels and the Appellate Body have undertaken in connection with the word "necessary" as it appears in Article XX of the GATT 1994 in analyzing whether a measure is "more trade restrictive than necessary"within the meaning of Article 2.2 of the TBT Agreement.[242]

181. In particular, the term "necessary" is used in Article XX of the GATT 1994 in a very different context than in TBT Article 2.2. Under Article 2.2 of the TBT Agreement, a panel is inquiring as to whether a measure that fulfills a legitimate objective is "**more trade-restrictive** than necessary" to fulfill that objective. Under GATT Article XX, the question is whether the **measure** is"necessary"protect human, animal or plant life or health or public morals or to secure compliance with laws or regulations. There are at least three important contextual differences. First, the question under Article XX is whether the measure **itself** is necessary, whereas under TBT Article 2.2 the question is whether the amount of trade-restrictiveness of the measure is necessary. Second, the analysis under TBT Article 2.2 involves alternatives that are two otherwise WTO-consistent measures; while to the extent that alternatives are compared under Article XX, the WTO-inconsistent measure (for which the exception is being invoked) is compared to a hypothetical measure that is WTO-consistent.[243] Third, unlike under GATT Article XX, it is the complaining party (not the defending party) that has the burden of establishing that the measure is "more trade-restrictive than necessary" under TBT Article 2.2.[244]

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[241] Indonesia First Written Submission, paras. 77, 86-89.

[242] U.S. First Written Submission, paras. 266-268.

[243] In this regard, Indonesia drastically understates the difference between the GATT Article XX and TBT Article 2.2 when it states that "both provisions allow Members to have in place measures that restrict trade so long as . . ." Indonesia Answer to Q58(a), para. 119. GATT Article XX justifies a Member's breach of the GATT while Article 2.2 is an obligation that Members must conform to when applying TBT measures that restrict trade.

[244] The EU contends that the fact that Article XX of the GATT 1994 constitutes an exception and Article 2.2 of the TBT Agreement a prohibition does not go to the question of how the text in Article 2.2 should be interpreted. EU Opening Statement, para. 15 (*EC – Tariff Preferences (AB)*, para. 98). The EU is incorrect in that which party bears

182. Further, there is no textual basis to apply the panel and Appellate Body's interpretive approach to Article XX of the GATT 1994 to Article 2.2 of the TBT Agreement. Under the Vienna Convention, the terms of a treaty must be interpreted based on their ordinary meaning in their context in light of the object and purpose of the treaty. The interpretation of TBT Article 2.2 based on the Vienna Convention is outlined above, and does not support reading the word "necessary" in the phrase "more trade-restrictive than necessary to fulfil a legitimate objective" in TBT Article 2.2 to have the same meaning as the word "necessary" in GATT Article XX(a), (b) or (d). In light of the different context in which the word "necessary" appears in Article 2.2 as compared to Article XX and the different circumstances surrounding conclusion of those provisions, it would not be appropriate to apply the same meaning or interpretive approach to both provisions.

b. There Is No Basis to Apply the Requirements of the Chapeau of GATT Article XX to the Interpretation of TBT Article 2.2

183. The EU carries this argument further, arguing that the Panel must apply the GATT Article XX chapeau when determining whether a measure is consistent with Article 2.2.[245] The EU first points out that the preamble to the TBT Agreement contains language similar to that used in the chapeau of Article XX. From this, the EU jumps to the conclusion that:

> ignoring the test set out in the chapeau of Article XX in the application of Article 2.2 of the TBT Agreement would risk leading to disparate legal evaluations between the GATT 1994 and the TBT Agreement which can hardly be intended. A measure which fails the test under the chapeau would not be justified under Article XX and, thus, be inconsistent with the GATT 1994, but not inconsistent with the TBT Agreement. Systemically, it would be counter-intuitive to have a more lenient standard under the TBT Agreement compared to the GATT 1994.[246]

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the burden of proof does affect the legal basis on which a measure may be found WTO-inconsistent. Under TBT Article 2.2, to establish a breach, the complaining party must establish that the measure is more trade-restrictive than necessary to fulfill a legitimate objective. Under Article XX(b), the complaining party need not establish the measure is not necessary to establish a WTO breach. It is the responding party's burden to establish that the measure is necessary and if it does not, the measure which was already found to breach a provision of the GATT, cannot be justified under Article XX. This difference calls for different legal elements that must be established for a measure to be considered "more trade-restrictive than necessary to fulfil a legitimate objective" versus not "necessary to protect human, animal or plant life or health."

[245] EU Answer to Q2, para. 8 ("The European Union has explained the reasons for which it would accord relevance to jurisprudence developed under Article XX of the GATT 1994 when interpreting Article 2.2 of the TBT Agreement. For the same reasons, and despite the fact that the language of the chapeau is not reproduced in Article 2.2 of the TBT Agreement, the European Union is of the opinion that existing jurisprudence on the chapeau of Article XX of the GATT 1994 is also relevant to the Article 2.2 analysis.").

[246] EU Answer to Q2, para. 12.

The EU's position is without merit, for at least four reasons.

184. First, the EU's argument ignores the most fundamental principle of treaty interpretation – that is, examining the text actually used by the drafters. The chapeau of Article XX is operative language: it plainly states that each one of the Article XX exceptions is "subject to the requirement" that the measure meets the requirements of the chapeau. In contrast, the TBT contains similar language in its preamble: the preambular language does not trigger any consequence under the agreement, but rather the preambular language may be used as an interpretive aid in construing operative provisions of the Agreement. If the drafters of the TBT agreement had intended to incorporate into TBT Article 2.2 (or any other TBT article) requirements similar to those in the Article XX chapeau, the drafters would have placed those requirements within the operative provisions of the agreement (just as the chapeau of Article XX is placed within the GATT 1994).

185. Second, the EU is simply wrong that its view prevents "disparate legal evaluations" between the two agreements. To the contrary, the EU's proposed reading would create disparate legal evaluations. The EU would require that each and every TBT measure meet the requirements of the Article XX chapeau. But there is no similar requirement that every measure within the scope of the GATT 1994 must meet the requirements of the Article XX chapeau. Rather, the chapeau requirements only apply in the event that a measure is inconsistent with a GATT obligation, and if the defending member then tries to justify that otherwise GATT-inconsistent measure under one of the Article XX exceptions.[247]

186. Third, the EU's argument ignores that the purpose expressed in the TBT chapeau (to prevent measures that unjustifiably discriminate between Members) in fact is addressed in the operative provisions of the TBT Agreement, though not in Article 2.2. Rather, Article 2.1 addresses such concerns by requiring that technical regulations provide to imported products treatment no less favorable than that provided to like products of national origin and to like products originating in any other country. In fact, if the EU's argument were accepted (and if thereby the Article XX chapeau requirements were somehow read into TBT Article 2.2), it would seem to make inutile Article 2.1 of the TBT agreement.

187. Fourth, it would be neither surprising nor alarming if analysis under the GATT 1994 and that under the TBT Agreement reached different results for the same measure. The two agreements contain different language and different obligations, and as a result can apply differently to the same measure. Indeed, if the GATT 1994 already addressed all of the matters covered under the TBT Agreement, there would have been no purpose in including the TBT Agreement within the Uruguay Round agreements.

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[247] Thus the EU's statement – that "A measure which fails the test under the chapeau would not be justified under Article XX and, thus, be inconsistent with the GATT 1994" – is wrong. The test under the chapeau only applies if a measure is first found to be inconsistent with a GATT obligation.

188. In sum, the EU's Article XX chapeau argument, like the contention that Article 2.2 should be interpreted based on the interpretation given to Article XX(b), is not consistent with the principles of treaty interpretation of customary international law. Indeed, the fact that the EU tries to graft this extra provision onto Article 2.2 shows just how inappropriate it is to base an interpretation of Article 2.2 on Article XX of the GATT 1994.

List of Exhibits

US-113	World Health Organization, "The Scientific Basis of Tobacco Product Regulation," WHO Technical Report Series 945 (2007)
US-114	Bryan-Jones & Chapman, "Political dynamics promoting the incremental regulation of secondhand smoke: a case study of New South Wales, Australia," BMC Public Health, 2006, 6:192 (July 21, 2006)
US-115	Centers for Disease Control and Prevention Cessation Web Page
US-116	Pasandaran & Sagita, "Some Indonesian Experts Say That Smoking Could Be Good for You," Jakarta Globe (December 14, 2010)
US-117	Kurniawati & Rachman, "Big Tobacco's Big Influence Keeps Indonesia Lighting Up," Jakarta Globe (November 1, 2010)
US-118	Camelia Pasandaran, "Indonesian Government Witnesses Say Tobacco Not Addictive," Jakarta Globe (January 5, 2011)
US-119	1994 U.S. Surgeon General Report, at 49 table 7
US-120	Wakefield, *et al.*, "The cigarette pack as image: new evidence from tobacco industry documents," Tobacco Control 2002; 11 (Supp I)
US-121	RJ Reynolds, Secret Strategic Research Report, "Younger Adult Smokers: Strategies and Opportunities" (February 29, 1984)
US-122	RJ Reynolds, "New Brands: Opportunities and Supporting Technologies" (1986)
US-123	Manning, *et al.*, "Flavoured cigarettes, sensation seeking and adolescents' perceptions of cigarette brands," Tobacco Control, 18: 459-465 (2009)
US-124	RJ Reynolds Letter to the New England Consulting Group (June 20, 1995)
US-125	Campaign for Tobacco-Free Kids Press Release, "Cuddle Up With Cancer: RJR's Candy-Flavored 'Winter Blend' Cigarettes Show Big Tobacco Hasn't Changed" (November 16, 2004)
US-126	American Association for Public Opinion Research ("AAPOR") Report on Online Panels, at 52 (March 2010)

US-127 Lewis, *et al.*, "Tobacco Industry Direct Marketing After the Master Settlement Agreement," Health Promotion Practice, supp to July 2004, vol 5, no. 3

US-128 Chung, *et al.*, "Youth Targeting By Tobacco Manufacturers Since The Master Settlement Agreement," Health Affairs, 21, no.2 (2002): 254-263

US-129 Campaign for Tobacco-Free Kids Press Release, "RJ Reynolds Launches New Flavored Cigarettes Circumventing Settlement With State Attorneys General" (May 22, 2007)