

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

**DS406**

**FIRST WRITTEN SUBMISSION OF  
THE UNITED STATES OF AMERICA**

**November 16, 2010**

## Table of Contents

I.	INTRODUCTION.....	1
II.	PROCEDURAL HISTORY.....	2
III.	FACTS.....	3
A.	Cigarette Smoking Trends in the United States.....	3
B.	The Harms and High Costs of Smoking in the United States. ....	4
C.	The High Cost of Prohibition.....	6
1.	A Sharp Increase in the Demand for Cessation Assistance Could Result in a Significant Stress for the U.S. Health Care System to Absorb. ....	7
2.	Any Increase in Black Market Cigarette Sales Would Produce a Range of Public Health Problems. ....	8
D.	The U.S. Cigarette Market.....	8
E.	The U.S. Flavored Cigarette Market. ....	9
1.	Menthol Cigarettes.....	10
2.	Clove Cigarettes.....	11
3.	Cigarettes With Other Characterizing Flavors.....	14
F.	The Survey Results Support the United States’ Position and Undermine the Indonesian One. ....	19
1.	Overview of Relevant Surveys.....	19
(a)	Surveys That Study Non-Menthol, Non-Clove Flavored Cigarettes .....	20
(b)	Surveys That Study Menthol and Clove Cigarette Use. ....	21
i.	<i>National Youth Tobacco Survey.</i> ....	21
ii.	<i>Monitoring the Future.</i> ....	21
iii.	<i>National Survey on Drug Use and Health.</i> .....	22
2.	The Reliable Survey Data Contradicts Indonesia’s Factual Conclusions .....	24
G.	Tobacco Legislation in the United States. ....	25
1.	Introduction. ....	25
2.	1998 Master Settlement Agreement . ....	26
3.	The MSA Is Not a Sufficient Regulatory Tool of Tobacco Products. . . .	27
4.	2006 State Attorneys General Consent Agreement with RJ Reynolds. . .	27
5.	The 2006 Consent Agreement Does Not Keep Cigarettes With Characterizing Flavors Other Than Tobacco or Menthol Off the U.S. Market. ....	28
6.	Federal Legislation Was Necessary to Keep Cigarettes with Characterizing Flavors Off the U.S. Market.. ....	29
H.	The Family Smoking Prevention and Tobacco Control Act. ....	32
1.	Background and Overview.....	32
(a)	Regulatory Standard Is “Appropriate for the protection of Public Health”.....	32
(b)	Scope Extends to All Aspects of Production, Marketing,	

	Distribution, and Sale.. . . . .	34
2.	Purpose.. . . .	37
	(a) Minimize the Harm Caused by Tobacco Products, in Particular by Reducing Smoking Among Youths.. . . .	37
	(b) Balance Against Countervailing Factors.. . . .	38
3.	Section 907 – Tobacco Product Standards.. . . .	39
4.	Mandate to Study the Public Health Impact of Menthol in Cigarettes. . .	43
I.	The United States’ Approach to Tobacco Regulation Is Consistent With Global Efforts. . . . .	44
IV.	LEGAL ARGUMENT.. . . .	45
A.	Section 907(a)(1)(A) Is Not Inconsistent With the National Treatment Provisions Contained in the GATT 1994 or the TBT Agreement . . . . .	45
B.	Section 907(a)(1)(A) Is Not Inconsistent With GATT Article III:4. . . . .	45
	1. Introduction. . . . .	45
	2. GATT Article III:4.. . . .	46
	3. Clove Cigarettes Are Not “Like” Tobacco and Menthol Cigarettes. . . .	47
	(a) Properties, Nature and Quality.. . . .	49
	i. Clove Cigarettes Have Distinct Physical Characteristics . . . . .	49
	ii. The Physical Characteristics of Menthol Cigarettes Are Not Like Clove Cigarettes.. . . .	52
	iii. Indonesia Is Incorrect That Clove Is a Flavoring Like Other Flavor Additives.. . . .	52
	(b) End-Uses. . . . .	54
	(c) Consumer Habits and Tastes. . . . .	54
	(d) International Tariff Classification. . . . .	56
	(e) Conclusion on Like Product.. . . .	57
	4. Section 907(a)(1)(A) Does Not Afford Less Favorable Treatment to Clove Cigarettes Based on Origin. . . . .	58
	(a) Section 907(a)(1)(A) Is Facially Neutral With Respect to Domestic and Imported Cigarettes.. . . .	59
	(b) Section 907(a)(1)(A) is Not <i>De Facto</i> Discrimination Based on National Origin . . . . .	59
C.	Section 907(a)(1)(A) Is Not Inconsistent With TBT Article 2.1.. . . .	62
D.	Conclusion on National Treatment Claims. . . . .	63
E.	Section 907(a)(1)(A) Is Not Inconsistent with TBT Article 2.2 . . . . .	64
	1. Legal Overview of Article 2.2. . . . .	64
	2. Congress Included Section 907(a)(1)(A) in the FSPTCA in Order to Fulfill a Legitimate Objective . . . . .	66
	(a) The Objective of Section 907(a)(1)(A) Is a Legitimate Objective for Purposes of Article 2.2 . . . . .	66
	(b) Congress Intended Section 907(a)(1)(A) to Protect the Public Health by Reducing Youth Smoking as Appropriate While Taking Into Account the Risk of Negative Consequences.. . . . .	66

	i.	Reducing Youth Smoking. . . . .	67
	ii.	Reducing Youth Smoking as Appropriate for the Protection of the Public Health, Taking Into Account the Risk of Negative Consequences. . . . .	68
	(c)	Section 907(a)(1)(A) Fulfills Its Legitimate Objective. . . . .	69
	i.	Section 907(a)(1)(A) Only Bans Cigarettes That Can Be Properly Considered “Starter” or “Trainer” Products Not Regularly Used by the U.S. Adult Population. . . . .	69
	ii.	Indonesia’s Arguments to the Contrary Are Unsupportable . . . . .	70
3.		Section 907(a)(1)(A) Fulfills the Legitimate Objective at the Level That the United States Finds Appropriate. . . . .	72
4.		Indonesia’s View of What the U.S. Legitimate Objective and Appropriate Level Are Is Not Supportable. . . . .	74
5.		Indonesia Has Failed to Establish That an Alternative Measure Fulfills the U.S. Legitimate Objective at the Level That the United States Considers Appropriate That Is Also Significantly Less Trade-Restrictive. . . . .	74
	(a)	The Proper Interpretation of the Meaning of What Is More Trade Restrictive Than Necessary to Fulfill the Legitimate Objective Must Flow From the Text of Article 2.2. . . . .	75
	(b)	The Meaning of the Term “Necessary” as Used in the 1994 GATT Article XX Context Is Not Instructive to Understanding the Meaning of TBT Article 2.2 . . . . .	77
	i.	GATT 1994 Article XX Does Not Inform as to the Meaning of TBT Article 2.2. . . . .	77
	ii.	Indonesia’s Analytical Approach Is Not Relevant to the Issue to Be Decided. . . . .	78
	(c)	Indonesia Has Failed to Adduce Any Evidence That Proves Section 907(a)(1)(A) Is More Trade-Restrictive Than Necessary. . . . .	79
6.		Indonesia’s Various Other Arguments Are Similarly in Error. . . . .	80
F.		Indonesia Has Not Shown That the United States Acted Inconsistently With Its Obligations Under TBT Article 2.5. . . . .	81
G.		Indonesia Has Not Shown That Section 907(a)(1)(A) Is Inconsistent With Article 2.8. . . . .	83
H.		Indonesia Has the Burden of Showing That the United States Acted Inconsistently With TBT Article 2.9. . . . .	84
I.		Indonesia Has Not Shown that the United States Acted Inconsistently With TBT Article 2.12. . . . .	85
J.		Indonesia Has Failed to Show That the United States Acted Inconsistently With TBT Article 12.3. . . . .	86
K.		Section 907(a)(1)(A) Is Justified Under Article XX. . . . .	88
	1.	Section 907(a)(1)(A) Falls Within the Scope of the Article XX(b) Exception. . . . .	89
	(a)	Section 907(a)(1)(A) Pursues a Policy Objective of Protecting Human Life and Health. . . . .	89

	(b)	Section 907(a)(1)(A) Is Necessary to Protect Human Life and Health.....	89
2.		Section 907(a)(1)(A) Meets the Requirements of the GATT 1994 Article XX(b) Chapeau. ....	91
	(a)	Section 907(a)(1)(A) is Not a Means of Arbitrary or Unjustifiable Discrimination Between Countries Where the Same Conditions Prevail. ....	92
	(b)	Section 907(a)(1)(A) Is Not a Disguised Restriction on International Trade.....	93
L.		The United States Has Not Nullified or Impaired Benefits Accruing Directly or Indirectly to Indonesia. ....	94
V.		CONCLUSION. ....	94
		List of Exhibits.....	95

## I. INTRODUCTION

1. Cigarettes, the product at issue in this case, present unique risks. As Gro Harlem Brundtland, former Director General of the World Health Organization, reportedly noted, a cigarette is the only consumer product that “when used as directed kills its consumer.”
2. Smoking kills more than 5 million people worldwide every year in every country in the world. The United States is no exception – over 443,000 Americans die every year from smoking related causes – and 8.5 million of them currently suffer from smoking-caused illnesses. The U.S. Congress has rightly termed smoking a “public health crisis.”
3. However, determining how best to address this public health crisis is complex given that so many people continue to, legally, smoke cigarettes. An estimated 46 million U.S. adults are smokers, the vast majority of whom are chemically and psychologically dependent on their cigarettes. Imposing a complete ban on cigarettes, or even on a subset of products that have a significant share of the market, raises many complicated questions, both for the individual addict, the health care system, and the society at large. Accordingly, despite the grave threat smoking poses, the United States and no country in the world ever has seriously considered prohibiting all cigarettes.
4. One area that must be addressed is the particular problem of youth smoking. The vast majority of regular, addicted smokers started under the age of 18, and keeping young people from smoking is a priority of the U.S. Government. Unfortunately, young people are also a priority of the cigarette companies, who are constantly innovating to find new customers and are well-aware that young people are most vulnerable. As will be fully explained below, within the last ten years, the cigarette companies came upon a new strategy – flavoring cigarettes with different tastes and smells – chocolate, cherry, vanilla, etc. – in the hope of attracting new young smokers.
5. In 2009, after many years of debate, the U.S. Congress enacted the Family Smoking Prevention and Tobacco Control Act (“FSPTCA”). The FSPTCA is without question an anti-smoking law. None of the many new restrictions contained in the law provide any economic benefit to the cigarette companies, either domestic or foreign.
6. To address the particular problem of youth smoking, the U.S. Congress determined that it was not appropriate – for many reasons – to ban *all* cigarettes. Rather, the U.S. Congress needed to draw lines, balancing the relative benefits and risks to the public health. Indonesia challenges the particular line drawn in Section 907(a)(1)(A), which prohibits all cigarettes with a characterizing flavor (including clove flavor), but not tobacco or menthol, which tens of millions of Americans smoke every day.
7. This brief will go into great detail about the historical background that led the U.S. Congress to draw the line where it did and the evidentiary basis for its decision. Some basic points are clear.
8. This line was *not* drawn based on the national origin of products. The line was *not* drawn

based on protectionism (the entire law targets U.S. cigarette companies after all). Instead, the line *was* drawn to protect the public health based on evidence that certain products presented a unique risk to youth and the negative consequences of banning them were slight or non-existent. The evidence establishes that clove and other-flavored cigarettes such as cherry, chocolate or cola are especially appealing to young people. While many youths smoke conventional or menthol cigarettes – in fact the overwhelming number of them do – so does practically every U.S. adult smoker. Given the possibility of causing significant negative consequences, the U.S. Congress chose not to ban all cigarettes or menthol flavored cigarettes at this time. The decision to do so was consistent with protecting the public health. Likewise, the decision to ban clove cigarettes and the other flavored cigarettes was also done to protect the public health. WTO Members never intended that a measure of this sort would run afoul of the WTO obligations, and this measure is entirely consistent with those rules.

9. As to the claims in this case, the Republic of Indonesia (“Indonesia”) has failed to satisfy its evidentiary burden. With regard to national treatment, cloves cigarettes are not like products with cigarettes generally and menthol cigarettes specifically. Moreover, Indonesia has not provided evidence that the difference in treatment provided clove cigarettes and the non-banned products is less favorable based on origin. As such, the United States has acted consistently with its national treatment obligations. Equally clear is the fact that Indonesia has failed to satisfy its burden under Article 2.2 of the Agreement on Technical Barriers to Trade (“TBT Agreement”). In fact, it has not adduced any evidence whatsoever that a reasonably available alternative measure fulfills the U.S. legitimate objective at the level that the United States considers appropriate and that is significantly less trade restrictive. Similarly, Indonesia has fallen short of its burden of proving any of their other TBT claims as well.

## **II. PROCEDURAL HISTORY**

10. On April 7, 2010, the Indonesia requested consultations with the United States pursuant to Articles 1 and 4 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (“DSU”), Article XXII of the *General Agreement on Tariffs and Trade 1994* (“GATT 1994”), Article 11 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”), and Article 14 of the *Agreement on Technical Barriers to Trade* (“TBT Agreement”) regarding a United States measure applying to certain flavored cigarettes, including clove cigarettes. This request was circulated on April 14, 2010. Pursuant to this request, the United States and Indonesia held consultations on May 13, 2010. These consultations failed to result in a mutually satisfactory resolution to the dispute.

11. On June 9, 2010, Indonesia requested the establishment of a panel pursuant to Article 6 of the DSU (WT/DS406/2). The Disputes Settlement Body (“DSB”) established the Panel on July 20, 2010 with the standard terms of reference.

12. The Parties agreed to the composition of the panel on September 9, 2010. Brazil, Colombia, Dominican Republic, the European Union, Guatemala, Mexico, Norway and Turkey

have reserved their rights to participate in the Panel proceedings as third parties.

### III. FACTS

#### A. Cigarette Smoking Trends in the United States

13. Although the cigarette was invented in the early 19<sup>th</sup> Century, cigarette smoking (as opposed to cigar or pipe smoking) was still relatively rare in the United States at the turn of the century.<sup>1</sup> That changed with the close of World War I when soldiers, who widely consumed cigarettes for relief during the extremes of tedium and tension, came home addicted to cigarettes.<sup>2</sup> Cigarette smoking increased in popularity more or less on a straight trajectory until the 1960's, and has declined since that high point.<sup>3</sup> An estimated forty-six million adults (20.6% of the U.S. adult population) are current smokers.<sup>4</sup> An additional 3.5 million high school/secondary school age persons (19.5% of children 14-18) are current smokers.<sup>5</sup> However, more recent data suggests that even these numbers understate the problem.<sup>6</sup>

14. As elaborated below, it is unquestioned that all tobacco use, including smoking, is dangerous. Smoking causes, among other ailments, lung cancer, emphysema, and heart disease, and costs 1,200 Americans their lives every day.<sup>7</sup> In the FSPTCA, Congress properly found smoking to be “the foremost preventable cause of premature death in America,” and is a “public

---

<sup>1</sup> U.S. Surgeon General, *Reducing Tobacco Use*, at 30 (2000), Chapter 2 at Exhibit US-1.

<sup>2</sup> U.S. Surgeon General, *Reducing Tobacco Use*, at 32. Exhibit US-1.

<sup>3</sup> U.S. Surgeon General, *Reducing Tobacco Use*, fig. 2.1, at 33 (Adult per capita cigarette consumption and major smoking and health events, United States, 1900-1999). Exhibit US-1.

<sup>4</sup> Centers for Disease Control and Prevention (“CDC”), *Adult Cigarette Smoking in the United States: Current Estimate*, [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/adult\\_data/cig\\_smoking/index.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm). (CDC, Adult Cigarette Smoking in the United States”). Exhibit US-2; Dep’t of Health and Human Services, Proposed Rule on Required Warnings of Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,526 (November 12, 2010) (“FDA Proposed Rule on Warning Labels”). Exhibit US-3. The United States notes, however, there are other studies that put the figure much higher, at almost 70 million people.

<sup>5</sup> CDC, *Youth Risk Behavior Surveillance – United States, 2009*, MMWR, Vol 59, No. SS-5, at 10 (June 4, 2010), [cdc.gov/mmwr/pdf/ss/ss5905.pdf](http://cdc.gov/mmwr/pdf/ss/ss5905.pdf), Exhibit US-4.

<sup>6</sup> See *2009 National Survey on Drug Use and Health*, Volume I. Summary of National Findings, <http://www.oas.samhsa.gov/NSDUH/2k9NSDUH/2K9Results.htm>, (stating that in fact 58.7 million U.S. persons (adults and children) are current cigarette smokers). Exhibit US-88.

<sup>7</sup> CDC, “Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses-United States, 2000-2004,” MMWR 57(45):1226-1228 (November 14, 2008), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>, (“CDC, Smoking-Attributable Mortality, 2000-2004”), Exhibit US-6.



health crisis” in America.<sup>8</sup> Each day, about 3,600 children (ages 12-17 years old) in the United States try their first cigarette and an additional 1,100 children under 18 years of age become new regular, daily smokers.<sup>9</sup>

## **B. The Harms and High Costs of Smoking in the United States**

15. The high cost of smoking to the United States can be measured in many different ways:

- More than 400,000 people die prematurely each year because of their own smoking, with tens of thousands of additional unnecessary deaths from exposure to secondhand smoke.<sup>10</sup>
- More than 8.5 million people currently suffer from smoking-caused illness and disease.<sup>11</sup>
- Smoking-caused healthcare costs total close to \$100 billion each year, with U.S. Government health programs accounting for just under half of those smoking-caused health expenditures.<sup>12</sup>
- Productivity losses just from useful work lives being shortened by smoking-caused early death also total approximately \$100 billion, with massive additional economic losses from productive work lives curtailed even further by smoking-caused illness or disability, from smokers taking more sick days than nonsmokers, and from smokers being less productive when on the job, thanks to

---

<sup>8</sup> FSPTCA, sec. 2, findings 13, 29, Exhibit US-7.

<sup>9</sup> 2007 National Survey on Drug Use and Health (“NSDUH”), Vol. I Summary of National Findings, at Table 4.10A <http://oas.samhsa.gov/NSDUH/2k7nsduh/tabs/Sect4peTabs10to11.pdf> 2007. Exhibit US-5.

<sup>10</sup> CDC, *Smoking-Attributable Mortality, 2000-2004*, at Editorial Note, n.6, Exhibit US-6.

<sup>11</sup> CDC, “Cigarette Smoking-Attributable Morbidity – United States, 1999-2000,” MMWR 52(35), at 842 (September 5, 2003), <http://www.cdc.gov/mmwr/PDF/wk/mm5235.pdf>, Exhibit US-8. As noted by the U.S. Surgeon General, “[s]moking harms nearly every organ of the body, causing many diseases and reducing the health of smokers in general,” causing at least ten different types of cancer, four different types of cardiovascular disease, numerous respiratory diseases and harms, pregnancy complications and reproductive disorders (including stillbirths and fetal deaths), as well as a host of additional disorders . . .” CDC, *The Health Consequences of Smoking: A Report of the Surgeon General, 2004*, at 25 (2004), [http://www.cdc.gov/tobacco/data\\_statistics/sgr/2004/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm), Chapter 1 excerpted at Exhibit US-9.

<sup>12</sup> Zhang, X., et al., “Cost of Smoking to the Medicare Program, 1993,” *Health Care Financing Review* 20(4), at 184-187 (Summer 1999), Exhibit US-10.

cigarette breaks and their generally worse health.<sup>13</sup>

16. While U.S. smoking rates have declined over the past several decades, progress has slowed recently.<sup>14</sup> Adult smoking rates have stopped declining, and may have actually increased in 2008.<sup>15</sup> Similarly, youth smoking rates have also stopped declining, showing no significant change between the last two years.<sup>16</sup>

17. Young people are the critical demographic in efforts to decrease smoking as people become much less likely to begin smoking as they get older. In the United States, 80% of new smokers began when they were under 18, 16% of smokers begin smoking between the ages of 18 and 21, and 2.5% begin smoking between 22 and 25.<sup>17</sup> Less than 2% of smokers start smoking after age 25.<sup>18</sup>

18. If current trends in youth smoking are not improved, more than 19 million youth in the United States under the age of 18 will grow up to be addicted adult smokers and more than six million of them will die prematurely from smoking.<sup>19</sup>

---

<sup>13</sup> See, e.g., CDC, *Smoking-Attributable Mortality, 2000-2004*, Table. Annual deaths and estimates of smoking attributable mortality, years of potential life lost, and productivity losses by sex and cause of death – United States, 2000-2004, Exhibit US-6; Rumberger, *et al.*, *Potential Costs and Benefits of Smoking Cessation in the United States* (April 30, 2010), <http://www.lungusa.org/stop-smoking/tobacco-control-advocacy/reports-resources/cessation-economic-benefits/reports/US.pdf> (“[D]irect costs to the [U.S.] economy attributable to smoking were in excess of US\$298 billion, including workplace productive losses of approximately US\$67.5 billion.”) Article Abstract at Exhibit US-11.

<sup>14</sup> This appears to be in direct contrast to Indonesia where rates of smoking have soared in recent decades. See Wilson and Belford, “Indonesia Resists the Anti-Smoking Tide Elsewhere,” *NY Times*, at A6 (November 14, 2010) (“Indonesian smoking rates rose 47 percent in the 1990s. About 60 percent of adult men smoke. For cultural reasons, only 5 percent of women smoke – providing a sales growth opportunity.”). Exhibit US-12.

<sup>15</sup> CDC, “Cigarette Smoking Among Adults and Trends in Smoking Cessation-United States, 2008,” *MMWR* 58(44):1227-32 (November 13, 2009) <http://www.cdc.gov/mmwr/PDF/wk/mm5844.pdf>, Exhibit US-13.

<sup>16</sup> CDC, “Cigarette Among High School Students – United States, 1991-2009,” *MMWR* 59(26):797-801 (July 9, 2010) <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm>. Exhibit US-14.

<sup>17</sup> See Exhibit US-15 (reporting data collected by 2007 NSDUH, which can be accessed at <http://oas.samhsa.gov/nsduh/2k7nsduh/2k7Results.cfm>); see also *Youth and Tobacco: Preventing Tobacco Use among Young People: A Report of the Surgeon General*, Table 7 at 49 (1994), [http://sgreports.nlm.nih.gov/NN/B/C/L/Q/\\_/nnbclq.pdf](http://sgreports.nlm.nih.gov/NN/B/C/L/Q/_/nnbclq.pdf), excerpts at Exhibit US-16.

<sup>18</sup> See Exhibit US-15 (reporting data collected by 2007 NSDUH, which can be accessed at <http://oas.samhsa.gov/nsduh/2k7nsduh/2k7Results.cfm>).

<sup>19</sup> CDC, *Sustaining State Programs for Tobacco Control: Data Highlights 2006*, Table 1 at 11, [http://www.cdc.gov/tobacco/data\\_statistics/state\\_data/data\\_highlights/2006/index.htm](http://www.cdc.gov/tobacco/data_statistics/state_data/data_highlights/2006/index.htm), Exhibit US-17.

19. Notwithstanding immense educational efforts of federal, state, and local governments as well as numerous non-governmental organizations, many youths continue to downplay the dangers of smoking,<sup>20</sup> in part because of relentless advertising and marketing by cigarette companies.<sup>21</sup>

20. Nicotine is the primary addictive constituent in tobacco and tobacco smoke. Recent studies show that as quickly as within the first day of smoking, youth can exhibit signs of tobacco dependence and addiction.<sup>22</sup> As such, it is also very difficult for existing smokers to quit. A 2007 survey found that 60.9% of high school youth who smoke tried to quit smoking, but only 12.2% of them were successful.<sup>23</sup> Overall, nearly 2 in 5 smokers try to quit, but fewer than 10% succeed.<sup>24</sup>

### C. The High Cost of Prohibition

21. Notwithstanding the high cost of smoking, the U.S. Government has never seriously considered banning all cigarettes given the likelihood of serious public health problems as well as the other problems associated with prohibiting a product that tens of millions U.S. adults are addicted to and regularly consume.

22. The U.S. Government and the U.S. public health community has been well aware of this paradox for years. For example, when the U.S. Food and Drug Administration (“FDA”) first issued its 1996 tobacco rule (subsequently blocked by the U.S. Supreme Court, as discussed below) it noted that the abrupt removal of cigarettes and smokeless tobacco products from the

---

<sup>20</sup> Lindsay, “Psychosocial and Pharmacological Explanations of Nicotine’s ‘Gateway Drug’ Function,” *Journal of School Health*, vol 67, No. 4, at 123 (April 1997), Exhibit US-18.

<sup>21</sup> A *Journal of the National Cancer Institute* study found that teens were more likely to be influenced to smoke by cigarette marketing than by peer pressure. Evans, *et al.*, “Influence of Tobacco Marketing and Exposure to Smokers on Adolescent Susceptibility to Smoking,” *Journal of the National Cancer Institute* (October 1995), Exhibit US-19. A *Journal of the American Medical Association* study found that as much as a third of underage experimentation with smoking was attributable to tobacco company marketing efforts. Pierce JP, *et al.*, “Tobacco Industry Promotion of Cigarettes and Adolescent Smoking,” *Journal of the American Medical Assoc.*, 279(7):511-505, February 1998 [with erratum in *JAMA* 280(5):422, August 1998]. Exhibit US-20.

<sup>22</sup> DiFranza, *et al.*, “Initial Symptoms of Nicotine Dependence in Adolescents,” *Tobacco Control* 9, at 317 (September 2000), Exhibit US-21; DiFranza, *et al.*, “Symptoms of Tobacco Dependence After Brief Intermittent Use,” *Archives of Pediatric and Adolescent Medicine* 161(7), at 705 (July 2007), Exhibit US-22.

<sup>23</sup> CDC, “High School Students Who Tried to Quit Smoking Cigarettes – United States, 2007,” *MMWR* 58(16), at 428 (May 1, 2009), Exhibit US-23.

<sup>24</sup> *Factors Associated with Successful Smoking Cessation in US, 2000*, *American Journal of Public Health*, Vol. 97, Iss. 8, at 1503 (2007), Exhibit US-24.

market would pose serious risks to the health of individual users and the overall population.<sup>25</sup> In deciding against such action, FDA stated that rates and degrees of adult addiction “must be considered when developing a regulatory scheme that achieves the best public health result for these products.”<sup>26</sup> FDA identified the specific public health risks posed by sudden withdrawal of tobacco products to which tens of millions of adults are addicted:

The sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous. First, there could be significant health risks to many of these individuals. Second, it is possible that our health care system would be overwhelmed by treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users. Third, the agency also believes that, given the strength of the addiction and the resulting difficulty of quitting tobacco use, a black market and smuggling would develop to supply smokers with these products. It also seems likely that any black market products would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.<sup>27</sup>

**1. A Sharp Increase in the Demand for Cessation Assistance Could Result in a Significant Stress for the U.S. Health Care System to Absorb**

23. The sudden removal of all cigarettes, or a large class of cigarette products that tens of millions of people are addicted to, could result in a sharp spike in the number of those seeking assistance with cessation. Affected individuals may have difficulty accessing the healthcare system and products that would facilitate cessation. For example, if just 20% of the approximately 14 million adults currently addicted to menthol cigarettes tried to see a practitioner in the month after a ban went into effect, an additional 2.8 million visits would result. According to CDC data, there were 1.1 billion ambulatory care visits in 2008, of which 62% were to primary care providers.<sup>28</sup> 2.8 million visits would thus represent a significant increase in the number of primary care visits – a significant stress for the system to absorb.

---

<sup>25</sup> Dep’t of Health and Human Services, *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. 44,396, 44,413 (August 28, 1996). Exhibit US-25.

<sup>26</sup> *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. at 44,413. Exhibit US-25.

<sup>27</sup> *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. at 44,413. Exhibit US-25.

<sup>28</sup> Hing, *Visits to Primary care Delivery Sites: United States, 2008*, NCHS Data Brief, at 1 (October 2010), <http://www.cdc.gov/nchs/data/databriefs/db47.pdf>, Exhibit US-26.

## 2. Any Increase in Black Market Cigarette Sales Would Produce a Range of Public Health Problems

24. Banning all cigarettes – or any type of cigarette favored by a large portion of U.S. smokers – could significantly increase the existing black market for cigarettes and all the attendant contraband trafficking and other illegal activity. There is already a sizeable black market for cigarettes in the United States. The Treasury Department’s Alcohol and Tobacco Tax and Trade Bureau (“TTB”) estimates that around \$2 billion dollars in federal excise tax revenue is lost each year due to this black market.<sup>29</sup>

25. The expansion of a black market could result in numerous problems, including:

- Safety declines: Cigarettes may be even less safe than those that are currently being sold in the U.S. market.<sup>30</sup>
- Youth access to tobacco products increases: Federal and state laws in the United States include a number of provisions designed to restrict the access of youth to tobacco products, such as proof of age requirements, penalties for retailers that sell to minors, penalties for minors that purchase cigarettes, and bans on self service displays in establishments that are not adult only. The black market would have none of these provisions designed to restrict access by youth.
- Crime increases: Black markets and their associated criminal activities are associated with a substantial number of other public health and societal costs such as violence, incarcerations, etc. These costs would rise as the black market expanded.

26. Accordingly, any plan to prohibit all cigarettes or a cigarette product with significant market share must be done with appropriate caution.

### D. The U.S. Cigarette Market

27. The U.S. market is dominated by “tobacco-flavored” cigarettes, which accounts for the vast majority of the market share, and menthol cigarettes, which accounts for, by one account,

---

<sup>29</sup> *Department of the Treasury Report to Congress on Federal Tobacco Receipts Lost Due To Illicit Trade and Recommendations for Increased Enforcement*, at 6 (February 4, 2010), <http://www.ttb.gov/pdf/tobacco-receipts.pdf>, Exhibit US-27.

<sup>30</sup> *See Pappas, et al*, “Cadmium, lead, and thallium in smoke particulate from counterfeit cigarettes compared to authentic US brands,” *Food and Chemical Toxicology*, Vol. 45, Issue 2, at 202 (February 2007) (indicating that illicit cigarettes contain high levels of heavy metals, such as cadmium, lead and thallium). Exhibit US-28.

26% market share.<sup>31</sup>

28. The overwhelmingly majority of cigarette sold in the United States are produced by U.S. companies comprising of only 2.9% of market share in 2009.<sup>32</sup> Two companies, Phillip Morris USA and Reynolds American Inc. (the result of a 2004 merger between RJ Reynolds and Brown & Williamson) comprise approximately 77% of the U.S. market.<sup>33</sup> The next largest competitor, Lorillard, comprises 12.4% of the market.<sup>34</sup>

29. Phillip Morris owns Marlboro, the leading cigarette brand family in the United States, whose market share alone was 41.8% in 2009. One of the Marlboro sub-brands is a menthol brand, although it has a relatively small market share in the menthol cigarette market. RJ Reynolds's market share consists of a number of conventional (i.e., "tobacco-flavored") brands, such as the Camel brand family, and two menthol brands, Kool and Salem. Lorillard's market share consists mainly of menthol cigarette sales from its Newport brand but also produces several non-menthol cigarettes as well. In 2006, 350.6 billion individual cigarettes were consumed in the United States.<sup>35</sup>

#### **E. The U.S. Flavored Cigarette Market**

30. As noted above, the vast majority of cigarettes sold in the United States have, in the terms of the FSPTCA, a characterizing flavor of tobacco. However, as explained below, cigarettes with a characterizing flavor of menthol, and, to a lesser extent, clove oil, have been sold in the United States for some time. In the years preceding the enactment of the FSPTCA, however, there was a sudden increase in the number of characterizing flavors being included in cigarettes sold or given away in the United States.<sup>36</sup> These flavors, which included chocolate, vanilla, and

---

<sup>31</sup> U.S. Federal Trade Commission ("FTC"), *Cigarette Report for 2006*, at Table 1A (2009), Exhibit US-29; Phillip Gardiner, "The African Americanization of menthol cigarette use in the United States, *Nicotine & Tobacco Research*, Vol. 6, Supp. 1, at S55 (February 2004) ("The African Americanization of US Menthol Use"). Exhibit US-30.

<sup>32</sup> Cigarettes: Domestic and Imported, 2000-2009, Exhibit US-31.

<sup>33</sup> See Philip Morris USA, *Cigarette Brand Market Share*, available at: [http://www.philipmorrisusa.com/en/cms/Company/Market\\_Information/default.aspx](http://www.philipmorrisusa.com/en/cms/Company/Market_Information/default.aspx), excerpts at Exhibit US-32; Reynolds American Inc., *Investor Fact Sheet*, available at: <http://www.reynoldsameric.com/invest.cfm>, excerpts at Exhibit US-32.

<sup>34</sup> Lorillard, Inc., *SEC Form 10-Q Quarterly Report for the Quarterly Period Ended September 30, 2010*, available at: <http://investors.lorillard.com/phoenix.zhtml?c=134955&p=irol-sec>, excerpts at Exhibit US-32.

<sup>35</sup> FTC, *Cigarette Report for 2006*, at Table 1A (2009), Exhibit US-29.

<sup>36</sup> Jane Lewis and Olivia 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 244 (February 2006) ("A Look at Flavored Cigarettes Promoted by Mainstream Brands") ("Flavored line extensions of popular cigarette

cinnamon, were added to tobacco, menthol, and clove-flavored cigarettes to create new products.<sup>37</sup>

## 1. Menthol Cigarettes

31. Menthol is a chemical compound extracted from the peppermint plant, grown predominantly in China and India, or produced by synthetic or semisynthetic means.<sup>38</sup>

32. Menthol cigarettes were first introduced into the U.S. market in the mid-1920's, although they did not gain any significant market share until the late 1950's.<sup>39</sup> By the mid 1970's, the menthol cigarette category had grown to approximately one-quarter of the U.S. cigarette market volume, but has remained relatively flat since that time, and in 2009 represented 26.8% of overall cigarette sales according to one source.<sup>40</sup>

33. As noted in above, menthol cigarettes are attractive to adults and children alike. Of the approximately 20% of American adults, an estimated 31% smoke menthol cigarettes.<sup>41</sup> Survey data discussed below in section III.F indicate that approximately 31% of youth smokers smoke menthol cigarettes, although that number could be higher.<sup>42</sup> African-Americans are much more likely than other racial or ethnic groups to smoke menthol cigarettes; 82% of African-Americans smokers use menthol cigarettes compared with 23.3% of White smokers.<sup>43</sup>

---

brands – specifically, Camel's Exotic Blends, Kool's Smooth Fusions, and Salem's Silver Label – are a recent tobacco industry innovation.”). Exhibit US-33.

<sup>37</sup> See section III.E(3).

<sup>38</sup> See Philip Morris USA Inc., *Written Submission to the Food and Drug Administration's Tobacco Products Scientific Advisory Committee (“TPSAC”) on Use of Menthol in Cigarettes*, at 13 (June 30, 2010) (“Phillip Morris's Menthol Submission to TPSAC”), excerpts at Exhibit US-34; American Lung Association, *Tobacco Policy Trend Alert, From Joe Camel to Kauai Kolada – the Marketing of Candy-Flavored Cigarettes*, at 1 (July 2005, updated May 2006), <http://slati.lungusa.org/reports/CandyFlavoredUpdatedAlert.pdf>, (“American Lung Association's Candy-Flavored Cigarette Alert”), Exhibit US-35.

<sup>39</sup> *Phillip Morris's Menthol Submission to TPSAC*, at 29, excerpts at Exhibit US-34; see also *American Lung Association's Candy-Flavored Cigarette Alert*, at 1, Exhibit US-35.

<sup>40</sup> *Phillip Morris's Menthol Submission to TPSAC*, at 29, excerpts at Exhibit US-34.

<sup>41</sup> *CDC's Cigarette Smoking Among Adults and Trends in Smoking Cessation – United States, 2008*, Exhibit US-13; Caraballo, *Menthol and Demographics* (March 30, 2010). Exhibit US-36.

<sup>42</sup> *Menthol and Demographics*. Exhibit US-36.

<sup>43</sup> Caraballo, *Menthol and Demographics* (March 30, 2010). Exhibit US-36; see also Gardiner, *The African Americanization of US Menthol Use*, at S55. Exhibit US-30.

34. Although menthol cigarettes are not banned, they are, like all cigarettes, unquestionably harmful products. The general public’s use of menthol cigarettes, and the methods of advertising and marketing of the product by cigarette companies, remain a significant concern of Congress, FDA, as well as health advocates, and continues to be the subject of intense study in the United States. In particular, Congress, in Section 907(e) of the FSPTCA, instructed a statutorily-created committee, the Tobacco Products Scientific Advisory Committee (“TPSAC”), to “issue a report and recommendation on 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.” TPSAC’s review of the issue is ongoing.

## 2. Clove Cigarettes

35. Indonesian companies first started exporting clove cigarettes, also known as “kreteks,” to the United States in 1968.<sup>44</sup> Although the vast majority of clove cigarettes consumed in the United States appear to be Indonesian imports, the United States understands that there is at least one domestic company, Nat Sherman, that manufactured a clove cigarette prior to Section 907(a)(1)(A) taking effect.<sup>45</sup>

36. Clove cigarettes are made from tobacco compounded with about 30-40% minced cloves and have a pungently sweet odor and taste.<sup>46</sup> PT Djarum, which claims that it controlled 70% of the pre-FSPTCA clove cigarette market in the United States, describes its product as the following:

It is not just the cloves that make kretek special, but also the secret sauce that adds to its enjoyment. Blending the unique taste of tobacco, fruit and herb extracts, and other natural flavorings, some say the kretek sauce recipe is more closely guarded than that of Coca Cola. Known only by two or three members of each kretek company, the sauce is used to *soften* the bite of tobacco and the pungency of clove. And, to further enhance the flavor, the tip of the kretek is *sweetened*. All adds to a *richer and fruity* taste, *sweet-scented* aroma and *pleasant* aftertaste than

---

<sup>44</sup> CDC, “Epidemiologic Notes and Reports Illnesses Possibly Associated with Smoking Clove Cigarettes,” MMRW Weekly, 34(21) 297-9 (May 31, 1985) (“CDC Article Regarding Epidemiology and Illnesses Possibly Associated with Cloves”), <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000549.htm>, Exhibit US-37.

<sup>45</sup> See *Letter from Larry Sherman to Customers* (September 17, 2009), Exhibit IND-13.

<sup>46</sup> Guidotti, *et al*, “Clove Cigarettes: the Basis for Concern Regarding Health Effects,” *The Western Journal of Medicine*, at 221 (August 1989) (“Clove Cigarettes: the Basis for Concern”), Exhibit US-38. As discussed below in section III.E(2), clove cigarettes have significantly different physical properties from other cigarettes on the U.S. market.



any regular cigarettes, and well-appreciated by kretek connoisseurs.<sup>47</sup>

37. In addition to producing cigarettes only flavored with clove oil, manufactures produced and exported clove cigarettes with additional flavorings, including vanilla, chocolate, coconut, and strawberry.<sup>48</sup>

38. One of the active ingredients in clove oil is eugenol, a common topical anesthetic used in dental procedures.<sup>49</sup> Clove cigarettes are sweetly aromatic, and smoking the product may cause some numbing of the mouth to occur.<sup>50</sup> The effect of eugenol is to remove much of the unpleasantness of cigarette smoking for new smokers.<sup>51</sup> As such, “[t]he clove cigarette is nearly ideal in design as a ‘trainer’ cigarette for capturing young people as smokers.”<sup>52</sup>

---

<sup>47</sup> Demirtas, “Djarum Cigarettes & Cigars,” <http://www.demirtas.com.tr/Djarum.htm> (emphasis added), Exhibit US-39.

<sup>48</sup> See *Djarum Cigarettes & Cigars* (listing vanilla and cherry flavored clove cigarettes) Exhibit US-39; Carrie M. Carpenter, *et al*, “New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies,” *Health Affairs*, Vol. 24, No. 6, at 1602 (Nov./Dec. 2005) (“New Cigarette Brands with Flavors that Appeal to Youth”) (noting that, as of October 2004, Kretek International and PT Djarum were collectively marketing clove cigarettes with the following flavors: vanilla, chocolate, mint, herbal, cherry, coconut, and strawberry) Exhibit US-40.

<sup>49</sup> Guidotti & Laing, “Clove Cigarettes,” *The Western Journal of Medicine*, at 538 (August 1992) (“Clove Cigarettes”), Exhibit US-41; *CDC Article Regarding Epidemiology and Illnesses Possibly Associated with Cloves*, Exhibit US-37.

<sup>50</sup> *Clove Cigarettes*, at 537, Exhibit US-41; *Clove Cigarettes: the Basis for Concern*, at 222, Exhibit US-38.

<sup>51</sup> *Clove Cigarettes*, at 537, Exhibit US-41.

<sup>52</sup> *Clove Cigarettes: the Basis for Concern*, at 226, Exhibit US-38; see also Susan Farrer, “Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes,” *National Institute on Drug Abuse (“NIDA”)*, Vol. 18, No. 2 (August 2003) (“Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes”) (“Clove cigarettes are sometimes referred to as ‘trainer cigarettes’ and may serve as ‘gateway’ products that introduce young people to smoking.”) Exhibit US-42; *CDC Article Regarding Epidemiology and Illnesses Possibly Associated with Cloves* (“Use of clove cigarettes may be changing the smoking patterns of American teenagers. Some researchers have suggested that eugenol anaesthetizes the backs of smokers’ throats and tracheas, permitting deeper inhalation and possibly encouraging smoking in person who might otherwise be dissuaded by the harshness of regular cigarettes.”) Exhibit US-37; *Clove Cigarettes*, at 538 (“Of equal concern has been the potential for conditioning smoking behaviour among adolescents. Clove cigarettes are a less noxious smoking habit because of their acceptable taste and an aesthetic effect on mucous membranes that lessening discomfort. The habit has been associated with many social trends important among adolescent peer groups . . . . As such, clove cigarettes may represent a dangerous potential for initiating previously inexperienced smokers to the habit.”) Exhibit US-41; Committee on Substance Abuse, “Hazards of Clove Cigarettes,” *Pediatrics*, Vol 88, at 395 (1991) (“Clove cigarettes should be suspected as a gateway drug because of their properties and the manner in which they are smoked. Because the eugenol in the clove cigarette acts as a topical anesthetic to the posterior oropharynx, it reduces the noxious elements of smoking. Thus it may facilitate the learning of smoking techniques, both regular inhalation and the deep inhalation toking technique used in marijuana smoking. In addition, the aroma and mystique of the use of

39. Confirming that view, adolescent users report that they prefer clove cigarettes to tobacco-flavored ones, and that “they perceive clove cigarette smoke as smoother, despite the perceived harshness of the tobacco used and the higher content of tar.”<sup>53</sup> However, the initial smoking experience with clove cigarettes is not always pleasurable to mature adults because the taste and odor can be overwhelming.<sup>54</sup>

40. Clove cigarettes are at least as dangerous as non-clove cigarettes, if not more so. Studies indicate that people inhale more deeply, increasing the amount of nicotine extracted from each cigarette, making it possible for smoker to achieve comparable blood concentrations of nicotine, even though clove cigarettes contain less nicotine per cigarette than do conventional brands.<sup>55</sup> Moreover, other scientific research has found that smoking clove cigarettes also produces higher levels of other potentially harmful constituents than regular cigarettes.<sup>56</sup>

41. Smoking clove cigarettes has also been linked to fads.<sup>57</sup> In the 1980's smoking clove cigarettes became popular among young Americans, particularly in California, and consumption spiked, with imports rising from 16 million dollars in value in 1980 to 150 million dollars in

---

clove cigarettes have made them very popular among those nondrug-using adolescents who are seeking to be accepted by and participate in the experiences of a drug-using peer group.”) Exhibit US-43.

<sup>53</sup> *Clove Cigarettes: the Basis for Concern*, at 226, Exhibit US-38; *see also id.*, at 226 (“More acceptable taste and anesthetic effect of clove cigarettes may make the first experience with smoking more enjoyable.”).

<sup>54</sup> *Clove Cigarettes: the Basis for Concern*, at 226, Exhibit US-38.

<sup>55</sup> Scientific research, using conventional smoking-machine analysis, has found that clove cigarettes produce more nicotine, tar and carbon monoxide than conventional cigarettes. *Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes*, Exhibit US-42; *see also CDC Article Regarding Epidemiology and Illnesses Possibly Associated with Cloves* (“Exposure to tar, nicotine and carbon monoxide is higher from clove cigarettes than from regular American cigarettes.”), Exhibit US-37; Malston, *et al.*, “Clove Cigarette Smoking: Biochemical, Physiological, and Subjective Effects,” *Pharmacology Biochemistry and Behavior* 74(3): 739-45 (February, 2003), <http://www.ncbi.nlm.nih.gov/pubmed/12543240> Exhibit US-44.

<sup>56</sup> *See* Polzin, *et al.*, “Determination of eugenol, anethole, and coumarin in the mainstream cigarette smoke of Indonesian clove cigarettes,” *Food & Chemical Toxicology* 45(10): 1948-53 (October 2007), <http://www.ncbi.nlm.nih.gov/pubmed/17583404> Exhibit US-45; Stanfill, *et al.*, “Quantification of flavor-related compounds in the unburned contents of bidi and clove cigarettes,” *Journal of Agricultural & Food Chemistry* 54(22): 8580-88 (November 1, 2006), <http://www.ncbi.nlm.nih.gov/pubmed/17061837>. Exhibit US-46.

<sup>57</sup> Guidotti, *et al.*, “Clove Cigarettes: Development of the Fad and Evidence for Health Effects,” *Current Topics in Pulmonary Pharmacology and Toxicology*, vol. 2, at 1, Exhibit US-47; *Clove Cigarettes: the Basis for Concern*, at 226, Exhibit US-38.

1984.<sup>58</sup> However, a health scare linked to smoking clove cigarettes in the middle part of that decade reduced sales in the United States drastically.<sup>59</sup>

42. As elaborated in section III.F, clove cigarettes are far more attractive to youth smokers than adult smokers with very few people using them after the age of 26.<sup>60</sup> Studies indicate that people who do smoke clove cigarettes tend to smoke them in addition to more conventional U.S. brands.<sup>61</sup>

### 3. Cigarettes With Other Characterizing Flavors

43. Although menthol has been the sole flavor to maintain permanent market penetration for the latter half of the 20th century, the concept of using flavored cigarettes to expand the cigarette market has been a strategy of the cigarette companies for many years.<sup>62</sup> For instance, as early as the 1970's, cigarette companies were considering a number of flavors, including cinnamon, anise, coffee, popcorn, marshmallow, tutti-frutti, and, notably, clove.<sup>63</sup>

44. A previously secret internal Philip Morris presentation in 1992 discussed the benefits of

---

<sup>58</sup> *Clove Cigarettes: the Basis for Concern*, at 220, 222-225, Exhibit US-38; see also *Clove Cigarettes*, at 537, Exhibit US-41; *CDC Article Regarding Epidemiology and Illnesses Possibly Associated with Cloves* (stating that sales increased from 12 million in calendar year 1980 to 150 million in fiscal year 1984). Exhibit US-37.

<sup>59</sup> *Clove Cigarettes*, at 537, Exhibit US-41; *CDC Article Regarding Epidemiology and Illnesses Possibly Associated with Cloves* (noting that between March 1984 and May 1985, 12 cases of severe illnesses possibly associated with smoking clove cigarettes were reported to CDC), Exhibit US-37; *Clove Cigarettes: the Basis for Concern*, at 220 (noting that several cases of pulmonary diseases associated with the clove smoking fad in the 1980's have been described) Exhibit US-38.

<sup>60</sup> See also CDC, *Men and Young Adults Most Likely Multi-Product Tobacco Users* (Aug 9, 2010), [http://www.consumeraffairs.com/news04/2010/08/tobacco\\_use.html](http://www.consumeraffairs.com/news04/2010/08/tobacco_use.html) Exhibit US-48.

<sup>61</sup> Substance Abuse and Mental Health Services Admin., *National Household Survey on Drug Abuse, 2001*, Vol. 1, Ch. 4. <http://oas.samhsa.gov/nhsda/2k1nhsda/vol1/chapter4.htm#4.spec> (Data of 2001 indicates that 75% of clove smokers and bidis (and Indian cigarette product) also smoke regular tobacco cigarettes), Exhibit US-49.

<sup>62</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603 Exhibit US-40; *A Look at Flavored Cigarettes Promoted by Mainstream Brands*, at 244, Exhibit US-33 (“[Previously secret] industry documents show that tobacco companies have researched and developed flavored cigarettes off and on for decades.”); *American Lung Association’s Candy-Flavored Cigarette Alert*, at 1 (“Phillip Morris introduced New Leaf, a wintergreen menthol cigarette, in 1970; Brown & Williamson introduced Lyme, a lime-flavored menthol cigarette, in 1971; and American Tobacco introduced Twist, a lemon-flavored menthol cigarette, in 1973. None of these cigarettes gained a significant share of the market largely due to consumers preferring other un-flavored brands.”) Exhibit US-35; *A Look at Flavored Cigarettes Promoted by Mainstream Brands*, at 244, (noting that Kretek International’s Dreams brand had marketed clove cigarettes with additional flavors prior to the sudden emergence of the flavored brands discussed in this section). Exhibit US-33

<sup>63</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1604, Exhibit US-40.

flavored cigarettes:

there has been a flavor-variety explosion in virtually every category of consumables except cigarettes. ...New flavors could cut across current and menthol segments, creating a new category. ...The concept (new flavors) could have the potential to be the most innovative change in cigarette marketing, reviving taste enjoyment and conscious purchase – selection excitement.<sup>64</sup>

45. Internal corporate documents produced by U.S. cigarette companies establish that the companies intended that such products would appeal to youth.<sup>65</sup> A Brown & Williamson report from 1972 suggested consideration of developing cola-flavored and apple-flavored cigarettes, stating: “[i]t’s a well-known fact that teenagers like sweet products. Honey might be considered.”<sup>66</sup> Brown & Williamson’s consumer research in 1984 revealed notable agreement among respondents that flavored cigarettes would be much more popular among young and inexperienced smokers.<sup>67</sup> A 1993 Lorillard document observed: “Growing interest in new flavor sensations (i.e. soft drinks, snack foods) among younger adult consumers may indicate new opportunities for enhanced flavor tobacco products that could leverage Newport’s current strength among younger adult smokers.”<sup>68</sup> An undated RJR document describing the early development of flavored cigarettes concludes: “[f]lavored cigarettes appeal to women...[and] younger smokers.”<sup>69</sup>

46. Industry research findings suggest that young and novice smokers might be especially vulnerable to these flavored cigarettes. In 1992, Phillip Morris tested several flavors among young adult smokers (male, ages 18-24; female, ages 18-34) and identified a number of possible attractions to consumers, including increased social acceptance via pleasant aroma and aftertaste, increased excitement (for example, sharing flavors), smoking enjoyment, and a “high curiosity to

---

<sup>64</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603 (quoting the internal Phillip Morris document entitled Philip Morris, “New Flavors Qualitative Research Insights,” October 1992, Bates no. 2023163698–2023163710, [tobaccodocuments.org/pm/2023163698-3710.html](http://tobaccodocuments.org/pm/2023163698-3710.html) (23 August 2005)) Exhibit US-40. As a result of various domestic litigation, U.S. cigarette companies were forced to disclose many internal documents regarding marketing strategies, nicotine manipulation, etc.

<sup>65</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603, Exhibit US-40.

<sup>66</sup> *American Lung Association’s Candy-Flavored Cigarette Alert*, at 3 (citing Marketing Innovations Inc. Project Report. Youth Cigarette – New Concepts (September 1972), Bates No. 170042014) Exhibit US-35.

<sup>67</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603, Exhibit US-40.

<sup>68</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603, Exhibit US-40.

<sup>69</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603, Exhibit US-40.

try factor.”<sup>70</sup>

47. Young adult smokers represented an emerging “corporate priority” beginning in the late 1980s as an engine for industry market growth.<sup>71</sup> In a report titled “Products of the 90’s,” RJ Reynolds authors emphasized the need to target products toward young smokers, and specifically to ensure “‘that conventional products have appeal to 18-24 year olds,’ as well as to provide ‘choices which are very different from current products.’”<sup>72</sup>

48. In 1999, RJ Reynolds launched the Camel Exotic Blends line. The original cigarettes: Twist (“splash of citrus flavor”), Crema (“a hint of vanilla”), and Izmir Stinger (berry flavored), were followed in 2000 with the release of Cinnzabar (“a touch of cinnamon and spice”).<sup>73</sup> By 2005, RJ Reynolds had released sixteen additional flavored brands:<sup>74</sup>

Name	Flavor(s)	Year of Introduction	Limited Edition
Mandarin Mint	Orange/Mint	2001	No
Dark Mint	Chocolate/Mint	2001	No
Mandalay Lime	Lime	2002	Yes
Aegean Spice	Spice	2002	Yes
Beach Breezer	Watermelon	2003	Yes
Margarita Mixer	Lime	2003	Yes
Midnight Madness	Champagne	2003	Yes
Bayou Blast	Berry	2003 & 2004	Yes
Kauai Kolada	Pineapple/Coconut	2004	Yes

<sup>70</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603, Exhibit US-40.

<sup>71</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603, Exhibit US-40.

<sup>72</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603-04, Exhibit US-40. As elaborated below, the proliferation of new flavored brands comes at a time when advertising and marketing restrictions in the 1998 MSA have made it more difficult to target young smokers. These increased restrictions prompted manufacturers to turn to product innovations to attract new smokers. *New Cigarette Brands with Flavors that Appeal to Youth*, at 1607-08, Exhibit US-40.

<sup>73</sup> *American Lung Association’s Candy-Flavored Cigarette Alert*, at iii & 2, Exhibit US-35; see also *A Look at Flavored Cigarettes Promoted by Mainstream Brands*, at 246, Exhibit US-33 (“[V]anilla-flavored Crema is described as delivering a ‘creamy, indulgent flavor that offers an intriguing and pleasurable smoking experience.’”).

<sup>74</sup> *American Lung Association’s Candy-Flavored Cigarette Alert*, at iii, Exhibit US-35.

Twista Lime	Citrus/Lime	2004	Yes
Warm Winter Toffee	Toffee	2004	Yes
Winter Mochamint	Peppermint/Mocha	2004	Yes
Back Alley Blend	Bourbon	2004	Yes
Snakeyes Scotch	Liquor	2005	Yes
Blackjack Gin	Liquor	2005	Yes
Screwdriver Slots	Liquor	2005	Yes

49. As indicated, many of these products were offered in limited quantities, either for a particular event or a season, as was the case with the berry-flavored “Bayou Blast,” which was offered during two successive Carnival (Mardi Gras) seasons, and the champagne-flavored “Midnight Madness,” which was offered in the month before New Year’s 2004.<sup>75</sup> The limited availability of these products “provides further evidence of the cigarette companies’ intent for these products to function as ‘starter cigarettes, rather than as regular brands intended to create and foster brand loyalty.’”<sup>76</sup>

50. In 2004, a leading U.S. business newspaper reported that sweet-flavored cigarettes were “one of the hottest new product categories in the tobacco industry.”<sup>77</sup> Consistent with this assessment, RJ Reynolds’ Camel brand family experienced a 9.8% sales volume increase for 2004.<sup>78</sup>

---

<sup>75</sup> *American Lung Association’s Candy-Flavored Cigarette Alert*, at 2, Exhibit US-35; *Flavored Cigarettes Promoted by Mainstream Brands*, at 249, Exhibit US-33. For further information on liquor-flavored cigarettes in particular, see American Lung Association, Tobacco Policy Trend Alert Addendum, *Alcohol-Flavored Cigarettes – Continuing the Flavored Cigarette Trend* (May 2006), <http://slati.lungusa.org/alerts/Alcohol-Flavored-Addendum.pdf>, Exhibit US-50.

<sup>76</sup> See *New Cigarette Brands with Flavors that Appeal to Youth*, at 1608, Exhibit US-40. See also 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 1211 (July 2008) (“Klein Article”) (“The majority of older adolescent and young adult smokers who used flavored cigarettes reported using on only 1-2 days per month, suggesting flavored cigarette use may be complementary to usual smoking behaviors. This patten of use is in agreement with the marketing of flavored cigarettes as an indulgence reserved for special occasions, mimicking the positioning of premium spirits and cigars.”). Exhibit US-51.

<sup>77</sup> *Flavored Cigarettes Promoted by Mainstream Brands*, at 244 (citing Vanessa O’Connell, “Massachusetts Tries to Halt Sale of ‘Sweet’ Cigarettes,” *Wall Street Journal* (May 20, 2004), at B1). Exhibit US-33.

<sup>78</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1601, Exhibit US-40.

51. Following the success of RJ Reynolds’ new products, in 2004 Brown & Williamson began adding flavors to their menthol cigarettes, including a berry flavor (“Midnight Berry”) and a chocolate flavor (“Mocha Taboo”).<sup>79</sup> By 2008, ACNielsen,<sup>80</sup> found that at least four U.S. cigarette companies were producing flavored cigarettes: RJ Reynolds (22 brands), Lorillard (2 brands), Liggett & Myers (1 brand), and Smokin’ Joes (1 brand).<sup>81</sup> ACNielsen also reports that Dreams, a Belgian company, was selling two flavored brands,<sup>82</sup> as well as two Indonesian clove cigarette manufactures: Darshan (15 brands) and Djarum (2 brands).<sup>83</sup>

52. As noted above, the internal documents of the cigarette companies indicate that the industry intended these products to be attractive to young Americans. The evidence establishes that this is in fact the case.

53. Additives that sweeten the taste of cigarettes promote youth initiation and help young occasional smokers to become daily smokers.<sup>84</sup> In surveys conducted in 2004, use of flavored products was highest for 17-year-olds (22.8%) and 18- to 19-year-olds (21.7%) and lowest for smokers 40 to 54(6.2%) and smokers 55 and older (0.8%).<sup>85</sup> Among the 3 flavored lines, Camel Exotic Blends was more commonly used than the other two.<sup>86</sup> According to the Klein Article:

Despite cigarette manufacturers’ claims that flavored products were developed and marketed solely for adults, 17-year-olds were over twice as likely to have used

---

<sup>79</sup> *American Lung Association’s Candy-Flavored Cigarette Alert*, at 2, Exhibit US-35.

<sup>80</sup> ACNielsen is a global marketing firm headquartered in the United States.

<sup>81</sup> ACNielsen, Table 1: *Known and Possible “Flavored” Cigarette Brands Sold in the United States, 2008*, Exhibit US-52. Smokin’ Joes is a small, Native American cigarette manufacturer located on the Tuscarora Reservation in New York State, near Niagara Falls. <http://www.sjbrands.com/>

<sup>82</sup> ACNielsen, Table 1: *Known and Possible “Flavored” Cigarette Brands Sold in the United States, 2008*, Exhibit US-52.

<sup>83</sup> ACNielsen, Table 2: *“Flavored” Clove Brands Sold in the United States, 2008*, (noting that the two Indonesia companies were selling clove cigarettes flavored with: strawberry, cherry, cinnamon, vanilla, grape, mint, mango, black licorice, lemon lime, chocolate, and black cherry). Exhibit US-52.

<sup>84</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1607, Exhibit US-40; *A Look at Flavored Cigarettes Promoted by Mainstream Brands*, at 247 (Public health and tobacco control advocates contend that these candy flavored cigarettes “mask the taste of tobacco (or “sweeten the poison”), thereby making it easier for new smokers, 90% of whom are teenagers or younger, to take up the habit.”), Exhibit US-33; *see also Djarum Cigarettes & Cigars* (stating that its product includes a “sauce” specifically “to soften the bite of tobacco and the pungency of clove,” as well as a “sweetened” tip, collectively resulting in “a richer and fruit[er] taste, [a] sweet[er]-scented aroma and pleasant[er] aftertaste than any regular cigarettes”). Exhibit US-39.

<sup>85</sup> *Klein Article*, at 1212 Table 2. Exhibit US-51.

<sup>86</sup> *Klein Article*, at 1212 Table 2. Exhibit US-51.

flavored cigarettes as young adults aged 20-26. The creative packaging and enticing imagery of these flavored cigarette brands may make flavored products appealing to younger persons, many of whom are just learning how to smoke. Recent research speaks to the attractiveness of flavored products among this age group: in a study of college students, higher positive smoking expectancies were reported for flavored brands, with evidence that flavored products may be especially appealing among young adults susceptible to initiation or smoking escalation.<sup>87</sup>

#### **F. The Survey Results Support the United States’ Position and Undermine the Indonesian One**

54. Indonesia repeatedly claims that clove cigarettes are only smoked by adults and rarely, if ever smoked by youth.<sup>88</sup> The survey data generated in the last decade refutes this claim, and strongly supports the United States’ view that clove cigarettes are disproportionately used by youth smokers and are properly considered a “trainer” smoking product, just as chocolate, cherry, and coconut flavored cigarettes are. This is in direct contrast to the use patterns of menthols, which are heavily used by both adults and youths alike.

55. Specifically, the data, as highlighted in Exhibit US-53, at 7, shows:

- The rate of use of flavored cigarettes and cloves are highest among persons 25 and under (11.9% and 5.5%, respectively) and lowest for persons 26 and older (6.7% and 1%, respectively);
- As a percentage of smokers, menthol is only smoked slightly more by persons 25 and younger (31.2%) than persons 26 and older (27.3%), although there are far more adult menthol smokers than there are youth menthol smokers, as discussed above in section III.A.

#### **1. Overview of Relevant Surveys**

56. Direct evidence of use patterns of different types of flavored cigarettes by different groups of consumers can be found in the numerous surveys taken of cigarette use across different demographics in the United States. Given their popularity, it is not surprising that a large number of well-conducted surveys contain data on U.S. consumers’ use of menthol cigarettes. Although much less data exists on the use of clove cigarettes, a number of surveys have gathered data on the use of clove cigarettes. As discussed below, the major studies do not address the prevalence of other types of flavored cigarettes. However, there is some data on the use of these

---

<sup>87</sup> *Klein Article*, at 1211. Exhibit US-51.

<sup>88</sup> *See generally* Indonesia First Written Submission, paras. 92-103.



cigarettes as discussed below.

57. Each of the surveys discussed below contain slightly varying estimates on the use of tobacco products. Understanding the differences in methodology between the surveys can provide important contextual background in understanding the differences in the prevalence estimates. In this regard, Indonesia appears to misuse certain survey data, either relying on misleading information, or drawing the incorrect conclusions. Accordingly, the United States will briefly describe each of the most relevant, well-conducted surveys, describing any weaknesses, where relevant, and then provide an assessment of the data generated by the particular survey.

**(a) Surveys That Study Non-Menthol, Non-Clove Flavored Cigarettes**

58. Although many of the traditional surveys do not examine the new breed of flavored cigarettes, data on the use of these newer, flavored cigarettes can be obtained from two telephone-based surveys, the National Youth Smoking Cessation Survey (“NYSCS”) and the Assessing Hardcore Smoking Survey (“AHCSS”). The NYSCS was conducted from 2003-2005 and surveyed individuals age 17-26. The AHCSS was conducted from 2004-2005 and surveyed individuals age 25 and older. Data from these surveys was published by Klein, *et al.* in 2008 (“Klein Article”).<sup>89</sup>

59. As noted in Exhibit US-53, the Klein Article establishes that the rate of use of flavored cigarettes is almost twice as high among smokers under the age of 25 as smokers over the age of 25. As reported in the Klein Article, the NYSCS found that the highest reported use was by 17 year olds (22.8%) and 18-19 year olds (21.7%) compared with all other age groups.<sup>90</sup> In fact 17 year olds alone “were over twice as likely to have used flavored cigarettes as young adults aged 20-26. This comparison gets even more extreme as 17 year old smokers are compared with older and older smokers. For example, only 0.8% of smokers 55 and older reported using flavored cigarettes.”<sup>91</sup>

60. As such, the evidence strongly supports the view of the United States that cigarettes marketed with a characterizing flavor of chocolate, cherry, and the like are uniquely attractive to youth, and thus serve as “trainer” or “starter” cigarettes. This conclusion is supported by a number of scholarly articles reviewing the data reported by the Klein Article.<sup>92</sup>

---

<sup>89</sup> See Klein Article, Exhibit US-51.

<sup>90</sup> Klein Article, at 1211. Exhibit US-51. A similar age gradient was reported by the AHCSS. *Id.*

<sup>91</sup> Klein Article, at 1212 Table 2. Exhibit US-51.

<sup>92</sup> See section III.F.

**(b) Surveys That Study Menthol and Clove Cigarette Use**

**i. National Youth Tobacco Survey**

61. The National Youth Tobacco Survey (“NYTS”) was developed to provide the data necessary to support the design, implementation, and evaluation of state and national tobacco prevention and control programs.<sup>93</sup> In addition, NYTS data supplement other existing data sources that provide prevalence estimates for selected tobacco use behaviors and provide comprehensive data for both middle school and high school students (ages 9-21) that cover tobacco use (*i.e.*, cigarettes, bidis (Indian cigarettes), kreteks (clove cigarettes), cigars, tobacco pipes, and smokeless tobacco products). Survey administration takes place in school and procedures are designed to protect students’ privacy by assuring that student participation is anonymous and voluntary. Students complete a pencil and paper self-administered scannable questionnaire booklet. The NYTS studies students between the ages of 9 and 21 and does not have adult data.

62. The NYTS presents the most reliable prevalence data for youth smoking, as it is administered in the school rather than at home (where youth tend to under-report).<sup>94</sup> The NYTS is also useful because it provides recent data and asked specifically about clove cigarettes, which is important methodologically.<sup>95</sup> As the NYTS asks the same questions every 2-3 years for the past decade, the survey is useful in identifying trends.

63. As indicated in Exhibit US-53, the NYTS further confirms that youths in fact do smoke clove cigarettes. The NYTS indicates that among smokers age 12 to 21, the rate of individuals who have used a clove-cigarette has been relatively constant at approximately 11% between 2002 and 2009.<sup>96</sup>

**ii. Monitoring the Future**

---

<sup>93</sup> The NYTS data is collected in “Tobacco Use Among Middle and High School Students – United States, 2000-2009,” MMWR, Vol. 59, No. 33, 1063-1068 (August 27, 2010). Exhibit US-54. *See also* NYTS website for further information. [http://www.cdc.gov/tobacco/data\\_statistics/surveys/nyts/index.htm](http://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm).

<sup>94</sup> *See, e.g.*, Gfroerer, *et al.*, “Prevalence of youth substance use: the impact of methodological differences between two national surveys,” *Drug and Alcohol Dependence*, vol. 47, at 20 (1997) (“Prevalence of youth substance use: the impact of methodological differences between two national surveys”) (stating that the evidence supports that “[h]igher prevalence rates for some drugs in the MTF than the NHDSA have been attributed to youths’ reluctance to admit to use when interviewed in their homes, where parents may be present”). Exhibit US-55.

<sup>95</sup> The NYTS has never asked questions about other types of flavored cigarettes. NYTS is typically administered every two or three years. The 2002, 2004, 2006 and 2009 NYTS all included specific questions on clove cigarettes and menthol cigarettes.

<sup>96</sup> *See* Patterns of Use Among Menthol, Clove, and Other Flavored Cigarettes, at 7-8. Exhibit US-53.

64. Monitoring the Future (“MTF”) is a survey funded by the National Institute of Drug Abuse (“NIDA”) and conducted by the University of Michigan Research Center. According to the MTF website, the organization has conducted in-school surveys of nationally representative samples of (a) 12th-grade students each year since 1975 and (b) 8th- and 10th-grade students each year since 1991 (youth approximately aged 18, 16 and 14, respectively). In addition, beginning with the class of 1976, the project has conducted follow-up mail surveys on representative sub-samples of the respondents from each previously participating 12th-grade class. These follow-up surveys now continue well into adulthood.<sup>97</sup>

65. The MTF 12th-grade survey asked about the use of clove cigarettes from 2001-2009, while the 8th and 10th grade surveys asked about the use of clove cigarettes from 2001-2005. The MTF has similar attributes to the NYTS in that it presents recent, reliable data on youth clove smoking as it is also administered in the school and asks specifically about clove cigarette use.

66. As indicated in Exhibit US-53, the MTF further confirms that youths do smoke clove-cigarettes. The MTF indicates clove cigarettes being used by eighth, tenth, and twelfth graders in high school.<sup>98</sup>

### iii. *National Survey on Drug Use and Health*

67. The National Survey on Drug Use and Health (“NSDUH”) is a national in-home survey conducted by the Substance Abuse and Mental Health Services Administration (“SAMHSA”).<sup>99</sup> The survey gathers information on mental health and substance abuse from the non-institutionalized civilian population in the United States who are 12 years of age or older. Beginning in 1999, field interviewers began using a computer-assisted personal interviewing system to collect general information (*i.e.*, demographics, occupational status) on respondents. Questions about substance abuse are answered directly by respondents. The survey is conducted annually in all 50 states and the District of Columbia.

68. The NSDUH-published prevalence rates for the use of tobacco products as well as drugs are often lower for youth than in other surveys. It is thought that this may be the case because youth may under-report undesirable behaviors in studies conducted in the home, such as the NSDUH.<sup>100</sup>

---

<sup>97</sup> See generally <http://monitoringthefuture.org/new.html>.

<sup>98</sup> See Patterns of Use Among Menthol, Clove, and Other Flavored Cigarettes, at 9 Exhibit US-53.

<sup>99</sup> The surveys can be generally accessed at <https://nsduhweb.rti.org/>.

<sup>100</sup> See, e.g., *Prevalence of youth substance use: the impact of methodological differences between two national surveys*, at 20 (stating that the evidence supports that “[h]igher prevalence rates for some drugs in the MTF than the NHDSA have been attributed to youths’ reluctance to admit to use when interviewed in their homes, where

69. While NSDUH does under-report tobacco use, it remains a valuable tool for people studying tobacco use. For example, the NSDUH includes data on adults, which other surveys do not. It also surveys more individuals, meaning that it is possible to do some subgroup analyses that are not possible with other data sets.

70. Questions about the use of menthol cigarettes are typically asked each year. The 2002 and 2003 NSDUH contained a module (*i.e.*, a series of questions) on clove cigarettes, and is therefore the most reliable NSDUH surveys that examine clove cigarette use by youth and adults alike.<sup>101</sup> In other years, NSDUH has not directly asked respondents about clove cigarettes, which generates unreliable data, as explained below.

71. Indonesia puts great reliance on the 2007 NSDUH, which it claims supports the proposition that clove cigarettes are smoked entirely by the adult population. However, unlike the 2002 and 2003 NSDUH,<sup>102</sup> the 2007 and 2008 NSDUH only obtain information about the use of clove cigarettes through an indirect methodology, which seriously bias the data.

72. The 2007 and 2008 NSDUH asks active smokers (those who have smoked part or all of a cigarette in the past 30 days) the following question: “The next questions are about the brand of cigarettes you smoke – the brand is the name that is on the pack. During the past 30 days, what brand of cigarettes did you smoke **most often**?”<sup>103</sup> (emphasis in the original). The survey then lists 25 different tobacco brands (none of which are clove-flavored brands) and an option for “A brand not on this list.” If a respondent selects “A brand not on this list,” he or she is again asked to select the brand of cigarettes smoked **most often** (emphasis in the original) in the past 30 days, presented with a list of another 32 cigarette brands (none of which are clove-flavored brands) and, again, “A brand not on this list.” If the respondent again selects “A brand not on this list” for a second time, he or she is asked to type in the name of the cigarette **most often** in the past 30 days.

73. Answers obtained from these three questions are then used to calculate the variable CIG30BR2, which is used by Indonesia in Exhibit IND-3 to compare the use of clove, menthol and tobacco-flavored cigarettes. Such reliance is in error for the following reasons.

74. First, regular clove smokers might not identify themselves as such given the structure of the questions used in the 2007 and 2008 NSDUH reports. In order to report that he or she uses

---

parents may be present”). Exhibit US-55.

<sup>101</sup> See NSDUH 2002 Clove Tables. Exhibit US-56; NSDUH 2003 Clove Tables. Exhibit US-57.

<sup>102</sup> As well as the 2002, 2004, 2006 and 2009 the NYTS discussed above.

<sup>103</sup> Questions can be accessed at <http://www.icpsr.umich.edu/icpsrweb/ICPSR/studies/23782/documentation>

clove cigarettes, the respondent must answer “A brand not on this list” to two separate questions and then type in the name of the clove brand that he or she uses. Standard survey methodology techniques would caution against relying upon data obtained in such a manner for comparative purposes given that this technique introduces significant bias and thus likely under represents the frequency of use of clove cigarettes.

75. Second, the data cited by Indonesia in the 2007 and 2008 NSDUH are further biased again reporting the use of clove cigarettes since the survey only asks respondents what the brand he or she smokes most often is. As discussed above, and as acknowledged by Indonesia, the reality is that clove cigarettes are frequently used non-exclusively; that is, they are used with other tobacco products.<sup>104</sup> Accordingly, regular consumers of clove cigarettes will often not identify themselves as such in the 2007 and 2008 NSDUH surveys.

76. Other surveys, such as the 2002 and 2003 NSDUH surveys as well as the NYTS do not suffer from these flaws and are much better tools to understand the use of clove by youth, young adults, and adults in the United States.

77. As indicated in Exhibit US-53, clove cigarettes are much more widely used by youth (those younger than 18) and young adults (those aged 18-25). Their use drops off precipitously among those age 20 and older, however. This is in stark contrast to use patterns of menthol cigarettes, which are smoked by 31% of youth versus 27% of those 26 and older.

## **2. The Reliable Survey Data Contradicts Indonesia’s Factual Conclusions**

78. Indonesia has made a number of factual conclusions regarding the prevalence of the use of clove cigarettes. None of them supported by the data. Briefly:

- Indonesia argues that 0.0% of youth smokers smoke cloves.<sup>105</sup> The data presented by Indonesia do not support this claim, due to limitations in the data discussed above. The NYTS prevalence data suggest that approximately 11% of youth smokers smoked clove cigarettes according to the most recent surveys. The

---

<sup>104</sup> The same can be said of other non-menthol flavored cigarettes. In one study, individuals who smoked flavored cigarettes were asked what their usual brand of cigarettes was. The vast majority of those who reported smoking flavored cigarettes gave a brand that was not flavored as their usual cigarette. See *Klein Article*, at 1211. Exhibit US-51.

<sup>105</sup> Indonesia First Written Submission, at 27 (“Among active youth smokers, 0.0% smoke cloves.”) (relying on Exhibit IND-3, at 4); Indonesia Written Submission, at 27 (“Among active youth smokers, 2006-2008, zero had used kreteks.”) (relying on Exhibit IND-3, at 5). Interestingly, Indonesia also makes the somewhat contradictory argument that even though zero percent of youth consume clove cigarettes, 0.05% of the cigarettes actually smoked by youth in 2007 were clove-flavored. Indonesia First Written Submission, at 3, 12, and 24 (relying on Exhibit IND-3, at 2).

2003-2003 NSDUH data suggest that around 5-6% of youth smokers smoke clove cigarettes, consistent with the idea that the NSDUH tends to under-report tobacco use generally.

- Indonesia argues that among active smokers, just 0.2% smoke cloves.<sup>106</sup> The data presented by Indonesia do not support this claim, due to limitations in the data discussed above.
- Indonesia argues that clove, menthol, and tobacco-flavored (conventional) cigarettes all have similar age distribution, with the vast majority of all of these products (95-97%) used by adults.<sup>107</sup> The data presented by Indonesia do not support this claim, due to limitations in the data discussed above. Based on the data from NSDUH, clove cigarettes are strikingly more popular among youth and young adults, with almost no one over the age of 26 using the products. In contrast, menthol and conventional cigarettes are used fairly consistently across the age spectrum.

## **G. Tobacco Legislation in the United States**

### **1. Introduction**

79. For much of the 20<sup>th</sup> Century, the U.S. tobacco industry developed, marketed and sold its products under very little regulation. By the 1930s and 1940s, evidence began to mount on the harms associated with smoking and nicotine. In 1957 the Surgeon General of the United States officially declared the position of the U.S. Public Health Service that evidence pointed to a causal relationship between smoking and lung cancer. In 1962, President John F. Kennedy appointed a committee of experts to conduct a comprehensive review of the scientific literature, whose report in 1964, *Smoking and Health: Report of the Advisory Committee to the Surgeon General*, defined the risks associated with smoking and solidified and validated the growing public awareness of the dangers of smoking. The report found cigarette smoking responsible for a 70% increase in the mortality rate of smokers over non-smokers; estimated the average smokers had a nine- to ten-fold risk of developing lung cancer compared to non-smokers (heavy had at least a twenty-fold risk); and named smoking as the most important cause of chronic bronchitis and pointed to a correlation between smoking and emphysema, and smoking and coronary heart disease.<sup>108</sup>

---

<sup>106</sup> Indonesia First Written Submission, at 27 (relying on Exhibit IND-3, at 3).

<sup>107</sup> Indonesia First Written Submission, 18 (relying on Exhibit IND-3, at 7).

<sup>108</sup> See *Smoking and Health: The Report of the Advisory Committee to the Surgeon General of the Public Health Service*, U.S. Department of Health, Education, and Welfare, Public Health Service Pub. No. 1103, Part I (1964), pps. 28-29. Exhibit US -58.

80. Following the 1964 report to the Surgeon General, Congress enacted in 1965 the United States’ first major federal legislation, the Federal Cigarette Labeling and Advertising Act, which among other things required the first health warning labels on cigarettes sold in the United States. A series of similar pieces of legislation related to labeling and advertising was implemented over the next 20 or so years.

81. In the early 1990s, both FDA and Congress initiated investigations of the U.S. tobacco industry concerning the industry’s knowledge of, and efforts to conceal, the dangers of cigarettes, as well as their efforts to market cigarettes to children. As industry practices came to light, private and public litigation ensued seeking compensation for health problems associated with smoking.

## **2. 1998 Master Settlement Agreement**

82. One of Indonesia’s erroneous factual claims is that the FSPTCA was unnecessary to remove cigarettes with characterizing flavors from the U.S. market because a litigation settlement concluded between a number U.S. states and certain tobacco companies (and a subsequent agreement related specifically to some flavored cigarettes) already effectively removed them.<sup>109</sup> An understanding of the settlement and subsequent agreement belies this claim.

83. In 1994, the U.S. states of Mississippi and Minnesota, through their attorneys general, initiated litigation against the tobacco industry to redeem tobacco-related costs incurred by the public health systems. Soon followed by nearly every state in the country had filed suit. In November 1998, the attorneys general and other representatives of U.S. territories signed a Master Settlement Agreement (“MSA”) with the four largest U.S. tobacco manufacturers (Brown and Williamson Tobacco Corporation, Lorillard Tobacco Company, Philip Morris Incorporated, RJ Reynolds Tobacco Company, and Commonwealth Tobacco Company),<sup>110</sup> ending the four-year legal battle.

84. The MSA required annual payments to the states from the four signatory tobacco companies (and any other cigarette manufacturers or importers that voluntarily signed onto the agreement), which could be used at each individual state’s discretion. The base payments required by the MSA (subject to various adjustments) totaled \$206 billion through 2025. The MSA, also prohibits the signatories from engaging in brand-name sponsorships or advertising that targets young people (defined as persons under the legal smoking age in a given state); allowed for public disclosure of industry documents previously kept secret by the signatories; and

---

<sup>109</sup> Indonesia First Written Submission paras. 3, fn 6, 22, fn 29, 108.

<sup>110</sup> Liggett and Myers was the last of the major U.S. companies to sign on and was not an original signatory. The MSA allowed for more companies to sign on to the agreement, and 41 companies subsequently have signed on. See “Master Settlement Agreement.” Exhibit US–59.

required the dissolution of certain U.S. tobacco industry promoting organizations.

### **3. The MSA Is Not a Sufficient Regulatory Tool of Tobacco Products**

85. It is important to note the limitations of the MSA. First, and most relevant to the issues before this panel, the MSA did not ban any cigarettes or any type of cigarette, did not restrict the characteristics of any cigarettes and did not provide the signatory states with any new rights or powers to ban or regulate the characteristics of the cigarettes of any of the signatories. By signing the MSA, the signatories agreed not to market cigarettes to youths – but flavored cigarettes were not even mentioned in the MSA and no practices specifically relating to flavored cigarettes were banned or restricted under the settlement.

86. Second, the MSA can be enforced only by the signatory states, and its restrictions and requirements apply only to the cigarette manufacturers and importers who have signed onto the agreement.<sup>111</sup>

87. Third, although the MSA was adopted by a number of states, it provides no comprehensive regulatory authority. The MSA did not assign jurisdiction over regulating cigarettes and their marketing and sale to the FDA (or any other state or federal agency), as originally contemplated in the “global settlement agreement.”<sup>112</sup>

88. In short, the MSA is not the comprehensive regulatory tool originally envisioned by the state attorneys general and public health community. Although it is regarded as an important victory in holding tobacco companies accountable and effecting a shift in their practices, as with any litigation settlement, the MSA represents a compromise between the parties to the underlying lawsuits and does not provide a comprehensive regulatory scheme.<sup>113</sup>

### **4. 2006 State Attorneys General Consent Agreement with RJ Reynolds**

89. As discussed in section III.E(3), beginning in the late 1990s but primarily between 2001 and 2005, major U.S. cigarette companies (especially RJ Reynolds) began to market aggressively

---

<sup>111</sup> Fifty-five companies are currently signatories to the MSA.

<sup>112</sup> See *Tobacco in the Wake of the 1998 Settlement Agreement*, Steven A. Schroeder, N. Engl. J. Med., 350;3 (January 15, 2004), 294. Exhibit US-60.

<sup>113</sup> Congress implicitly noted this fact in its findings, stating that “Federal and State governments have lacked the legal authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.” FSPTCA Sec 2(7). Exhibit US-7.



new product lines of cigarettes with characterizing flavors.<sup>114</sup>

90. It was this new, prominent marketing of brands of cigarettes with characterizing flavors, which were not already well established in the U.S. market, that prompted the addition, in 2004, of the provision banning all cigarettes with characterizing flavors other than tobacco or menthol into predecessor legislation to the FSPTCA.<sup>115</sup>

91. This new line of flavored products also prompted the state attorneys general in Illinois and New York to lead an MSA-based investigation of RJ Reynolds, the U.S. cigarette company most actively using new characterizing flavors as a marketing strategy. Data gathered as part of the investigation revealed that more youth than adults were smoking these cigarette brands with characterizing flavors other than menthol or tobacco.<sup>116</sup> The investigation resulted in the allegation that RJ Reynold’s flavored cigarettes violated the MSA prohibition against marketing cigarettes to youth.<sup>117</sup>

92. As an alternative to litigation, in 2006 RJ Reynolds, but no other manufacturer of flavored cigarettes, entered into a formal Consent Agreement with MSA-signatory states, agreeing to pull its current flavored cigarettes off the market (the “2006 Consent Agreement”).<sup>118</sup> But RJ Reynolds retained the right to develop new cigarette brands with characterizing flavors in the future, subject to certain marketing and packaging restriction.

## **5. The 2006 Consent Agreement Does Not Keep Cigarettes With Characterizing Flavors Other Than Tobacco or Menthol Off the U.S. Market**

93. The 2006 Consent Agreement does not keep cigarettes with a characterizing flavor off the

---

<sup>114</sup> Although several manufacturers and importers – including Kretek International and Brown & Williamson – had flavored cigarettes on the U.S. market previously, the roll-out of flavored cigarettes in the early part of the decade was the first aggressive push to put flavored cigarettes on the market, apparently ushering in a new trend.

<sup>115</sup> Public health legislation to provide FDA with authority over tobacco products had been introduced since at least 1998, but the provision at issue here first appeared in both the U.S. Senate and House of Representatives legislation in 2004 (S. 2461 and H.R. 4433).

<sup>116</sup> See Klein Article. Exhibit US-51.

<sup>117</sup> The basis for the attorneys general claim that RJ Reynolds’s marketing of the flavored cigarettes violated the MSA is Section III(a) which provides: "Prohibition on Youth Targeting. No Participating Manufacturer may take any action, directly or indirectly, to target Youth within any Settling State in the advertising, promotion or marketing of Tobacco Products, or take any action the primary purpose of which is to initiate, maintain or increase the incidence of Youth Smoking within any Settling State." Exhibit US-59.

<sup>118</sup> 2006 Consent Agreement. Exhibit US-61.

U.S. market. After the 2006 Consent Agreement, RJ Reynolds still manufactured for sale in the United States at least 13 cigarettes with a characterizing flavor under various brands, with no related MSA or 2006 Consent Agreement enforcement efforts.<sup>119</sup> RJ Reynolds agreed only to pull some of its current flavored cigarette brands off the market in the signatory states, and agreed to limit the marketing and sale of any future cigarettes with certain flavor-related words or images used in their name, packaging or advertising to adult-only venues.<sup>120</sup>

94. Not only is the 2006 Consent Agreement inadequate to keep even RJ Reynolds from putting flavored cigarettes on the U.S. market, it has no application to manufacturers or importers other than RJ Reynolds. And it can be enforced against RJ Reynolds only by the attorneys general in the 40 states that officially signed onto the agreement.<sup>121</sup>

95. Another limitation of the 2006 Consent Agreement is that it is not conclusive with respect to whether flavored cigarettes are inconsistent with the terms of the MSA. RJ Reynolds specifically asserts in the 2006 Consent Agreement its view that the sale and marketing of the flavored cigarette brands banned under that agreement actually complies fully with the MSA.<sup>122</sup> Therefore, should the states seek to apply the MSA to prevent other MSA-signatory companies from marketing flavored cigarettes, the states would have to successfully settle or litigate in each case the issue of whether the marketing and sale of the specific cigarette brands with a characterizing flavor did in fact target youths. Re-litigating that question on a case-by-case basis every time a signatory company was found marketing and selling a cigarette with a characterizing flavor would not only be a drain on state resources but would not necessarily stop the marketing of the new cigarette brands with new characterizing flavors. Indeed, the separate enforcement efforts by different signatory states that decided to take action would likely lead to inconsistent interpretations and applications of the MSA across those states.

## **6. Federal Legislation Was Necessary to Keep Cigarettes with Characterizing Flavors Off the U.S. Market**

96. Despite the limitations of the MSA and the 2006 Consent Agreement, Indonesia suggests

---

<sup>119</sup> See Exhibit US-8 and Exhibit US-52.

<sup>120</sup> The flavored cigarettes that RJ Reynolds agreed in the 2006 Consent Agreement not to manufacture, market or distribute specifically for distribution or sale in the United States were brand styles among the Camel, Kool and Salem Brands with the exception of Basma, Samsun and Rare. 2006 Consent Agreement, para. 7, fn 3. Exhibit US-61.

<sup>121</sup> Forty states and the Mariana Islands currently have signed onto the 2006 Consent Agreement.

<sup>122</sup> The 2006 Consent Agreement states “Whereas, [R.J.] Reynolds asserts that it in good faith believes that its marketing, advertising and sale of the Investigated Cigarette Brand Styles fully complies with the MSA and Consent Decrees[.]” Exhibit US-61.

that these agreements render the ban contained in the FSPTCA unnecessary.<sup>123</sup> This is not the case. In fact, the ban was essential to remove cigarettes with a characterizing flavor from the U.S. market and to prevent the tobacco industry from penetrating the U.S. market with cigarettes with a characterizing flavor in the future.

97. It is clear that the MSA and the 2006 Consent Agreement with RJ Reynolds have failed to stop the marketing of cigarettes with characterizing flavors. For example, as noted previously, RJ Reynolds, itself, marketed at least 13 different new flavored cigarette brands after the Consent Agreement was executed. Kretek International and PT Djarum, which signed onto the MSA in 2001 and 1999 respectively, both marketed cigarettes with additional characterizing flavors such as cherry and vanilla after the 2006 Consent Agreement.<sup>124</sup>

98. In addition, state lists of cigarette brands show that numerous other cigarette brands with characterizing flavors were being sold in the United States right before the FSPTCA's prohibition on cigarettes with characterizing flavors other than tobacco or menthol went into effect on September 20, 2009.<sup>125</sup> Examples include flavored cigarette brands manufactured domestically (e.g., Nat Sherman's "A Touch of Clove"), flavored "bidi" cigarettes from India (with flavors such as coffee, peach, cherry, aniseed and chocolate), and flavored cigarette brands from the Netherlands, Belgium and Germany, as well as clove cigarettes from Indonesia.<sup>126</sup>

99. The continued sale of these flavored cigarette brands before the FSPTCA's prohibition went into effect directly contradicts Indonesia's implication in its First Written Submission that all of the cigarettes with "candy"-type flavorings had already been taken off the U.S. market because of the 2006 Consent Agreement between some of the MSA states and RJ Reynolds and that only pure clove-flavored cigarettes were still being sold.<sup>127</sup>

100. Moreover, the ban on characterizing flavors is essential to preventing cigarette manufacturers from introducing new brands of cigarettes with characterizing flavors to the

---

<sup>123</sup> Indonesia First Written Submission paras. 3, fn 6, 108.

<sup>124</sup> See, e.g., "Examples of cigarettes certified for Sale in the United States as of 2009," Exhibit US-62 (compiling data from the Office of Fire Prevention Control, New York State Department of State, Office of Fire Prevention Control, New York State Department of State, Cigarettes Certified by manufacturers as of 1/20/09 [current list available at <http://www.dos.state.ny.us/fire/cigarette.htm>] (Exhibit US-63) and the Office of the State Fire Marshall, State of Maine, List of Cigarettes Certified by the Maine Fire Marshal's Office by Manufacturer, Brand, Style/packaging & Recertification date As of 7/29/2009, <http://www.maine.gov/dps/fmo/documents/CigaretteCertification.pdf> ("Main Fire Safe Cigarette List"). Exhibit US-64; see also Exhibit US-52.

<sup>125</sup> Exhibit US-62.

<sup>126</sup> Exhibit US-62.

<sup>127</sup> Indonesia First Submission at 1, fn 6 and at 7, fn 29.

market in the future. The fact that some U.S. manufacturers and importers had pulled some of their cigarette brands with characterizing flavors off of the market before the ban went into effect in no way implies that they forever would keep such products off the market or that no new manufacturers or importers would not have introduced new flavored brands into the market.

101. To the contrary, the tobacco industry has evidenced its significant interest in marketing flavored cigarettes. Tobacco companies have heavily invested in the research and development of cigarettes with characterizing flavors and actively sought to market them however possible.<sup>128</sup> It is clear that cigarette companies remain ready, willing, and able to do all they can to increase their sales, including marketing that reaches and influences youth. Revealingly, the court in *United States v. Philip Morris et al.* in 2006 found with respect to the major tobacco manufacturers:

- “Defendants spent billions of dollars every year on their marketing activities in order to encourage young people to try and then continue purchasing their cigarette products in order to provide the replacement smokers they need to survive. Defendants’ expenditures on cigarette advertising and promotion have increased dramatically over the past decades, and in particular since signing the MSA.”<sup>129</sup>
- “After signing the MSA, Cigarette Company Defendants reported to the FTC significant increases in spending for newspapers (up 73%), magazines (up 34.2%), and direct mail (up 63.8%). Distribution of free cigarettes rose by 133.5%.”<sup>130</sup>
- “The evidence is clear and convincing – and beyond any reasonable doubt – that Defendants have marketed to young people twenty-one and under while consistently, publicly, and falsely, denying they do so.”<sup>131</sup>
- “Despite the provisions of the MSA, Defendants continue to track youth behavior and preferences and market to youth using imagery which

---

<sup>128</sup> See section III.E(3).

<sup>129</sup> *U.S. v. Philip Morris USA, Inc., et al.*, No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, para. 3301. Exhibit US-65

<sup>130</sup> *U.S. v. Philip Morris USA, Inc., et al.*, No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, para. 3026. Exhibit US-65

<sup>131</sup> *U.S. v. Philip Morris USA, Inc., et al.*, No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, para. 3296. Exhibit US-65

appeals to the needs and desires of adolescents.”<sup>132</sup> and “there is a reasonable likelihood that Defendants’ RICO violations [including marketing to youth and denying that they do so] will continue.”<sup>133</sup>

102. As explained below, the FSPTCA – by directly establishing many restrictions and requirements pertaining to cigarettes and their marketing and by providing FDA with extensive authority to establish new restrictions and requirements – works directly to prevent the tobacco industry from marketing its existing cigarette brands or developing and marketing any new brands in ways that will increase youth smoking initiation, reduce cessation among adults, otherwise increase total cigarette consumption, or increase the overall public health harms from smoking. The provision banning cigarettes with characterizing flavors other than tobacco or menthol is one important component of the FSPTCA’s comprehensive effort.

## **H. The Family Smoking Prevention and Tobacco Control Act**

### **1. Background and Overview**

#### **(a) Regulatory Standard Is “Appropriate for the Protection of Public Health”**

103. The FSPTCA authorizes the FDA to regulate the manufacturing, marketing, distribution and sale of tobacco products. The granting of such authority was the result of years of legislative effort to address the dangers of smoking, particularly among children and adolescents. Prior to enactment of the FSPTCA, the FDA in 1996 asserted authority to regulate tobacco products. The FDA had concluded that nicotine – and the products that deliver it to the body – fall under its statutory authority. The FDA issued regulations, later adopted in large part as part of the FSPTCA, including the establishment of 18 as the national minimum age to purchase tobacco products and the ban on free samples of tobacco products except in adult-only venues.

104. The FDA’s issuance of new rules marked a significant milestone in tobacco regulation; until that time, Congress had authorized the Federal Trade Commission to regulate tobacco products with respect to advertising, sale and distribution, but no oversight body with scientific expertise was authorized to regulate tobacco products specifically for the protection of public health.

105. In 1997, before the rules were fully implemented, U.S. tobacco companies challenged the FDA’s regulatory authority and in 2000 the U.S. Supreme Court invalidated the FDA’s rules,

---

<sup>132</sup> *U.S. v. Philip Morris USA, Inc.*, et al., No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, paras. 1607-1608. Exhibit US-65

<sup>133</sup> *U.S. v. Philip Morris USA, Inc.*, et al., No. 99-CV-02496GK (U.S. Dist. Ct., D.C.), Final Opinion, August 17, 2006, para. 1606. Exhibit US-65

finding that Congress had not granted the FDA the authority to regulate cigarettes and smokeless tobacco as customarily marketed.<sup>134</sup> In response, Congress devised legislation to grant authority to the FDA. The final FSPTCA legislation was not passed by both chambers of Congress and signed by the President until 2009, 13 years after FDA first promulgated its initial rules.

106. Significantly, Congress directed the FDA to apply a different standard to tobacco products than to any other product or device that it regulates. Following the 2000 Supreme Court ruling that the “safe and effective” standard could not be applied to tobacco products without requiring their removal from the market, Congress authorized the FDA to regulate tobacco products as appropriate for public health – and not according to a balance of the therapeutic or other benefits to individual users weighed against the risk of illness or serious harm to individual users (the approach used in the regulation of drugs, biologics and medical devices).

107. This standard addresses, and seeks to balance, an uncomfortable reality: tobacco products offer no therapeutic or other benefits to individuals, and yet millions of Americans are addicted to cigarettes and other tobacco products. Approximately 20% of American adults (46 million Americans) currently smoke cigarettes, and among them, 78.1% – approximately 36.4 million people – are daily smokers.<sup>135</sup>

108. This widespread addiction presents unique public health questions and concerns. While some health advocates urged the U.S. Government to ban all cigarettes – or some types that are heavily used, such as menthol-flavored cigarettes – Congress did not conclude that banning a product to which millions of Americans are addicted would be appropriate to protect the public health. As the FDA found in 1996:

Tobacco products have historically been legal and widely available in this

---

<sup>134</sup> The U.S. Supreme Court reasoned as follows: The FDA’s statutory charge is to ensure that drugs are “safe and effective” for the market. Were tobacco products to fall under the FDA’s jurisdiction, the FDA would be forced to ban all tobacco products, based on the FDA’s findings that the products were unsafe and dangerous. Therefore, the Court concluded, because Congress had foreclosed a ban on all tobacco products, and set up a series of regulations pertaining to tobacco products, it could not have intended for the products to fall under FDA regulatory authority and, therefore, be banned. The FDA argued that it could sanction tobacco products as “safe” to the extent that banning them would create greater risk to the public health. Significantly, the Supreme Court did not disagree with the claim that banning tobacco products entirely might cause a net increase in public health harms. However, this argument did not satisfy the Court because the Court found that the FDA’s governing legislation required that to determine a product to be “safe,” its therapeutic benefits must outweigh the risk of illness or serious injury at least for some consumers, and that standard would require FDA to ban cigarettes (regardless of the overall public health consequences of such a ban). In light of this Supreme Court finding, in the 2009 FSPTCA Congress expressly directed the FDA to apply a different standard to tobacco products than any other product or device that the FDA regulates. Because tobacco products have no therapeutic benefit, Congress determined that the FDA should regulate tobacco products and their marketing in a manner that is “appropriate to protect the public health,” working to ensure that any actions FDA takes under the authority provided by the FSPTCA will produce a net benefit to overall public health. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000). Exhibit US-66.

<sup>135</sup> Exhibit US-3.

country. It was only after millions of people became addicted to the nicotine in cigarettes and smokeless tobacco that health experts became fully aware of the extraordinary health risks involved in the consumption of these products. Consequently, tobacco use has become one of the most serious public health problems facing the United States today. Because of the grave health consequences of the use of tobacco products, some have argued that they should be removed from the market. However, a ban would have adverse health consequences and would not be likely to prevent individuals from gaining access to these products.<sup>136</sup>

The FDA further found that adverse health consequences could result if individuals suddenly were deprived of the nicotine that tobacco products deliver, and American health and pharmaceutical resources may not be able to provide adequate or sufficiently safe treatment for precipitous withdrawal.<sup>137</sup> Moreover the FDA concluded it was probable that a black market and smuggling would develop to supply addicted users with nicotine-delivering products that could be even more dangerous than those currently on the market legally.

109. Immediately banning access to all tobacco products – as the Supreme Court determined would be required under the FDA’s “safe and effective” standard – raised a number of countervailing issues with respect to the effect on the public health. Therefore, Congress determined that the regulation of tobacco products – including whether to ban certain products – must be applied based on a standard of the health benefits and risks to the population as a whole, and cannot properly be addressed solely through a standard based exclusively on the health effects for an individual user.

110. Accordingly, Congress granted the FDA authority in the FSPTCA to regulate tobacco products “as appropriate for the protection of the public health,” and notes that “[t]his new standard is more appropriate for inherently dangerous tobacco products than the standards of ‘safe’ or ‘safe and effective,’ which apply to other FDA-recognized products.”<sup>138</sup> Congress recognized that unique FDA authority was necessary to regulate tobacco products that are inherently dangerous with no health benefits but broadly used by the addicted members of the public.

**(b) Scope Extends to All Aspects of Production, Marketing,  
Distribution, and Sale**

111. Congress authorized the FDA to regulate tobacco products because pre-existing public

---

<sup>136</sup> 61 Fed. Reg. 44398 (August 28, 1996). Exhibit US-25.

<sup>137</sup> 61 Fed. Reg. 44398 (August 28, 1996). Exhibit US-25.

<sup>138</sup> HR Report, at 3. Exhibit US-67.

and private efforts to minimize the harms caused by tobacco use in the United States were clearly inadequate. In particular, the legislative history states that:

Past efforts to restrict the advertising and marketing of tobacco products to youth have failed to adequately curb tobacco use by adolescents. [The FSPTCA] provides the FDA with the authority it needs to promulgate comprehensive restrictions on the sale, promotion, and distribution of tobacco products, actions that most public health experts agree can significantly reduce the number of people who start to use tobacco and significantly increase the number of people who quit using tobacco.”<sup>139</sup>

The FSPTCA states further that a purpose of the Act is “to ensure that the Food and Drug Administration has the Authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco.”<sup>140</sup>

112. The FSPTCA authorizes the FDA to regulate the manufacture, marketing, distribution and sale of tobacco products “as appropriate for the protection of public health.”<sup>141</sup> As described in more detail below, Section 907(a)(1)(A) of the Act prohibits cigarettes containing a characterizing flavor other than tobacco or menthol.

113. The FSPTCA measures impose significant restrictions and requirements on every aspect of how tobacco products are manufactured, marketed, distributed and sold. Furthermore, it empowers the FDA to adopt additional regulations as appropriate. Ninety-seven percent of the cigarettes sold in the United States which are affected by these measures are U.S.-produced. The FSPTCA is primarily targeted at – and has real impact upon – the domestic tobacco industry.

114. The ban on characterizing flavors other than tobacco or menthol is just one important part of the comprehensive effort the FPSTCA establishes to minimize the public health effects of tobacco through the regulation of tobacco products. The Act – including the rule that cigarettes cannot contain a characterizing flavor other than tobacco or menthol – applies to all cigarettes, regardless of whether they are domestic products or imports (and, as noted, the vast majority of flavored cigarettes prohibited under the ban were U.S.-manufactured).<sup>142</sup>

115. The FSPTCA regulates manufacture of tobacco products directly through requirements such as those requiring tobacco products to be produced in sanitary facilities and to be

---

<sup>139</sup> HR Report, at 3. Exhibit US-67.

<sup>140</sup> FSPTCA, sec. 3(2). Exhibit US-7.

<sup>141</sup> FSPTCA, sec. 906(d)(1); sec. 906(e)(1)(A). Exhibit US-7.

<sup>142</sup> See section III.E(3).



unadulterated by contaminants<sup>143</sup> and indirectly by, for example, empowering the FDA to set new product standards to reduce or eliminate harmful ingredients and additives (including pesticide residue) or otherwise modify the design and characteristics of tobacco products if it is determined that such regulation is appropriate to protect the public health.<sup>144</sup>

116. The Act regulates marketing by, for example, establishing a range of advertising restrictions and requirements,<sup>145</sup> requiring warning labels and other disclosures,<sup>146</sup> and by authorizing the FDA to establish additional standards and restrictions related to the labeling, advertising, and promotion of tobacco products.<sup>147</sup>

117. The Act regulates the distribution and sale of tobacco products by establishing a federal minimum age of 18 for purchasing cigarettes,<sup>148</sup> generally banning free samples,<sup>149</sup> calling for FDA to establish a system of tracking and tracing all tobacco products from point of manufacture to point of sale,<sup>150</sup> and authorizing the FDA to implement additional requirements and restrictions on tobacco product distributions and sales.<sup>151</sup>

---

<sup>143</sup> FSPTCA sec. 909(a). Exhibit US-7.

<sup>144</sup> FSPTCA sec. 907(a)(4)(A)-(D). Exhibit US-7.

<sup>145</sup> FSPTCA sec. 906(d)(1). Exhibit US-7.

<sup>146</sup> FSPTCA sec. 201; sec. 904. Exhibit US-7.

<sup>147</sup> FSPTCA secs. 907, 910, 911. Exhibit US-7. In fact, the FDA just announced that beginning in October, 2012, only cigarette products complying with new labeling requirements will be sold in the United States. The new warning labels will feature graphic anti-smoking pictures and cover the half of the front of the cigarette box and the entire backside. They will replace less prominent warning labels which the United States has required for the last 24 years. “New, More Graphic Cigarette Labels Unveiled,” Washington Post, November 10, 2010. Exhibit US-86.

<sup>148</sup> FSPTCA sec. 906(d)(3)(A)(ii). Exhibit US-7.

<sup>149</sup> FSPTCA sec. 102(a)(2)(G). Exhibit US-7.

<sup>150</sup> FSPTCA sec. 920(b)(1). Exhibit US-7.

<sup>151</sup> Specific measures that apply to all cigarettes include (1) requiring manufacturers to disclose all ingredients and harmful or potentially harmful constituents in their cigarettes, the form and delivery method of nicotine, and any research into health, toxicological, behavioral, or physiological effects of tobacco products to the FDA and notify the FDA of any future changes to any of the above; (2) requiring manufacturers to provide all marketing research documents to the FDA; (3) requiring FDA review of all new types of cigarettes before they can enter the U.S. market unless they are substantially similar to products marketed before February 15, 2007; (4) prohibiting companies from promoting any cigarettes as lower-risk alternatives to other cigarettes or other tobacco products unless the FDA certifies that the marketing, sale and use of the allegedly “lower risk” cigarette is likely to improve public health; (5) mandating larger, more varied, and more prominent warning labels; (6) banning the sale of cigarettes in packages of less than 20 anywhere except adult-only facilities; (7) requiring most ads not in adult-only venues to be black text on white background only; and (8) prohibiting any branded merchandise or any

118. The FSPTCA also directs the FDA to establish two new entities: the Center for Tobacco Products (“CTP”) in the FDA, which is responsible for implementing the FSPTCA, and the Tobacco Products Scientific Advisory Committee (TPSAC), a 12-member body charged with advising the CTP on issues related to nicotine yields and other safety, dependence, or health issues related to tobacco products.<sup>152</sup>

## 2. Purpose

### (a) Minimize the Harm Caused by Tobacco Products, in Particular by Reducing Smoking Among Youths

119. The Purpose of the FSPTCA is to minimize the harmful effects of tobacco products – particularly by reducing youth smoking – including by authorizing the FDA to issue additional regulations on tobacco products as appropriate for the protection of the public health.<sup>153</sup>

120. Congress considered that goals consistent with protecting the public health include reducing the availability and appeal of tobacco products to young people<sup>154</sup> (the demographic group most likely to begin smoking);<sup>155</sup> ensuring that users of tobacco receive complete and accurate product information;<sup>156</sup> and developing standards to limit the harms caused by tobacco products.<sup>157</sup> Accordingly, the Act prohibits industry practices that especially appeal to young people and establishes strict labeling and product information standards to ensure that smokers are notified of the inherent risks.

121. The enumerated purposes of the FPSTCA are:

---

gifts given to consumers related to their cigarette purchases.

<sup>152</sup> FSPTCA sec. 917. Exhibit US-7.

<sup>153</sup> H. R. Rep. No. 111-58 at 3 (2009). Exhibit US-67. *See also* FSPTCA Sec 1(29) “It is in the public interest for Congress to adopt legislation to address the public health crisis created by the actions of the tobacco industry.” Exhibit US-7.

<sup>154</sup> *See, e.g.*, FSPTCA Sec 1(6) “Because 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;” *See also* FSPTCA Secs 1(20), (22) and (24). Exhibit US-7.

<sup>155</sup> *See, e.g.*, FSPTCA Sec 1(4) “Virtually all new users of tobacco products are under the minimum legal age to purchase such products.” Exhibit US-7. *See also* H. R. Report at 32 (citing FDA findings in the Preamble to the FDA’s 1996 rules and regulations, 61 Fed. Reg. 44398 (August 28, 1996)). Exhibit US-67.

<sup>156</sup> *See, e.g.*, FSPTCA secs 1(16), (40), (41), (42), and (43). Exhibit US-7.

<sup>157</sup> *See, e.g.*, FSPTCA Sec 1(36). Exhibit US -7.

- (1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing and distribution of tobacco products as provided for in this division;
- (2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;
- (3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;
- (4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;
- (5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;
- (6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;
- (7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;
- (8) to impose appropriate regulatory controls on the tobacco industry;
- (9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and
- (10) to strengthen legislation against illicit trade in tobacco products.<sup>158</sup>

As demonstrated by the list above, Congress intended the FSPTCA to be a broad-based approach to addressing the national health crisis caused by the use of tobacco products.

**(b) Balance Against Countervailing Factors**

---

<sup>158</sup> FSPTCA sec. 3. Exhibit US -7.

122. While the FSPTCA clearly pursues and promotes the public health goal of reducing adult smoking, it also includes specific limits that would prevent any immediate or entire removal of adult access to cigarettes already on the market and regularly used by large numbers of adult smokers. The Act precludes the FDA from prohibiting face-to-face sales of tobacco;<sup>159</sup> establishing a national age of older than 18 years to purchase tobacco products;<sup>160</sup> banning all products within a category of tobacco products (such as all cigarettes, or all smokeless tobacco products);<sup>161</sup> or requiring the reduction of nicotine yields of a tobacco product to zero.<sup>162</sup> Congress granted the FSPTCA broad authority to regulate tobacco, but tempered that authority by carefully drawn limits, given the prevalent use of tobacco products in the United States and the unique nature of the public health problem presented by nicotine addiction.<sup>163</sup>

123. The FSPTCA balances other interests, as well. For example, the Act tightens advertising regulations within the limits of tobacco manufacturers’ protected first amendment right to advertise tobacco products to adults.<sup>164</sup> The Act also balances federal and state governing prerogatives by preserving the ability of states to regulate tobacco products and prosecute tobacco companies for product liability.<sup>165</sup> Finally, the Act excludes tobacco leaf growers from FDA regulatory authority.<sup>166</sup>

### **3. Section 907 – Tobacco Product Standards**

124. Section 907 of the FSPTCA pertains to tobacco product standards. The purpose of the provision is to authorize the FDA to adopt product standards – including the elimination of an additive, constituent, or other component of a tobacco product – if it is determined that a standard is appropriate to protect the public health.

125. Section 907 also defines the standard at issue in this dispute: Section 907(a)(1)(A)

---

<sup>159</sup> FSPTCA sec 906(d)(3)(A)(i). Exhibit US-7.

<sup>160</sup> FSPTCA sec 906(d)(3)(A)(ii). Exhibit US-7.

<sup>161</sup> FSPTCA Sec 907(d)(3)(A). Exhibit US-7.

<sup>162</sup> FSPTCA Sec 907(d)(3)(B). Exhibit US-7.

<sup>163</sup> One of the enumerated purposes of the FSPTCA is “(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers.” Exhibit US-7.

<sup>164</sup> FSPTCA Sec 916. Exhibit US-7.

<sup>165</sup> FSPTCA Sec 916. Exhibit US-7.

<sup>166</sup> See FSPTCA Sec 901(c)(2). Exhibit US-7.

provides that cigarettes shall not contain a characterizing flavor other than tobacco or menthol. Section 907(a)(1)(A) states:

A cigarette or any of its component parts (including tobacco, filter, or a paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.<sup>167</sup>

126. Section 907(a)(1)(A) entirely blocks the availability of a product that is used by youth and hardly used by addicted adults, consistent with the overall purpose of the FSPTCA to minimize the harm of tobacco products and reduce youth smoking. Congress considered that such a ban is appropriate for the public health because the health benefits far outweighs the risk of harm. The significant health benefit is to eliminate a product that is particularly attractive to youth, with the effect of introducing them to nicotine or otherwise encouraging further tobacco use, and has low overall use by adults. The risk to the public health is negligible, because the number of adults addicted to cigarettes with characterizing flavors other than tobacco or menthol is negligible.

127. There are five key factual points to be made about Section 907(a)(1)(A). First, Section 907(a)(1)(A), on its face and as a matter of law, applies to all cigarettes, regardless of origin. It does not discriminate between domestic and imported products.

128. Second, Section 907(a)(1)(A), in fact, impacts upon both domestic and imported cigarettes. Section 907(a)(1)(A) precludes the major U.S. companies from manufacturing, marketing distributing or selling in the United States products which the industry has spent at over a decade developing, researching and marketing specifically to sell in the United States. Section 907(a)(1)(A) prevented U.S. manufacturers from profiting from their substantial investment in cigarettes with characterizing flavors.

129. U.S. tobacco manufacturers clearly intended to exploit a market for cigarettes with characterizing flavors, and Section 907(a)(1)(A) foreclosed that business opportunity. At the time Section 907(a)(1)(A) went into effect, U.S. manufacturers still had certified for sale in states across the country brands of cigarettes with a characterizing flavor other than tobacco or menthol. Even with advertising restrictions in place, the U.S. tobacco industry for 50 years has relentlessly sought to market and sell cigarettes to children and denied publicly and to the Federal

---

<sup>167</sup> FSPTCA sec. 907(a)(1)(A). Exhibit US-7.

government that it does so.<sup>168</sup> U.S. tobacco manufacturers were eager to exploit the market possibilities opened up by flavored cigarettes and that avenue of market penetration was cut off.

130. Section 907(a)(1)(A) impacts upon and severely disrupts the market plan of the major U.S. tobacco companies to use characterizing flavors as a new “hook” to attract the next generation of cigarette smokers. That the major U.S. companies realized they lost this battle and pulled a number of their characterizing flavors off the market in anticipation of the ban only proves, and does not negate, this reality.

131. The third key factual point is that Section 907(a)(1)(A) was determined, based on scientific evidence, to be an appropriate standard to protect the public health. Specifically, Section 907(a)(1)(A) is based on evidence that cigarettes with a characterizing flavor other than tobacco or menthol (1) are used by youths; (2) make tobacco products more attractive to youths and new users and thus likely increase the chance that they will move on to other tobacco products; and (3) are barely used by adults, and even then are used primarily as an “special occasion” cigarette and not as the daily cigarette to which adults are addicted.

132. The legislative record states that:

The Committee has reviewed the products that will be banned after 90 days under this section and has concluded that the ban will not lead to negative public health effects, because of *how affected products generally are used and because of their low overall use by adult smokers. Specifically, none of the cigarettes covered by the ban – including those with the characterizing flavors of fruit, chocolate or clove – is used regularly by a large number of addicted adult smokers.* Instead, these cigarettes tend to be used only occasionally, either by regular users of other products, by individuals who are experimenting with tobacco use, or by those who smoke only in certain social settings. *Given that few adult smokers ever use 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.* All of these factors – irregular, experimental and social setting use and low overall use with 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

---

<sup>168</sup> See *U.S. v. Philip Morris USA, Inc.*, et al., para. 3296. Exhibit US-65. Indonesia grossly understates the efforts of tobacco companies to target youth when it states that “[f]rom time to time tobacco companies did develop products that health advocates alleged were designed and marketed to youth. When concerns about these products were raised, these products were voluntarily removed from the market by their manufacturers or distributors.” Indonesia First Written Submission at 108. In fact, tobacco manufacturers, including Indonesian manufacturers of clove-flavored cigarettes, were marketing cigarettes with so-called “candy” flavors up until the ban went into effect in September 2009. Exhibits US-52 and US-62.

population.<sup>169</sup> (Emphasis added).

133. The fourth point is that Section 907(a)(1)(A) is not based on a determination that cigarettes with a charactering flavor are more or less safe or healthy for individual users. Section 907(a)(1)(A) is based on the determination that banning cigarettes with characterizing flavors other than tobacco or menthol will have positive benefits for the public health, in particular in curbing youth smoking, with negligible costs or risks to the public health. Although some evidence suggests that clove-flavored cigarettes in fact could be more dangerous than other cigarettes,<sup>170</sup> this was not the basis upon which clove-flavored cigarettes or other flavored cigarettes were banned. Congress has found that all cigarettes are inherently dangerous.<sup>171</sup> Instead, the point of Section 907(a)(1)(A) is to consider the relative risks and benefits to the health of the population as a whole.

134. Finally, the fifth key point with respect to Section 907(a)(1)(A) is that Congress identified a number of countervailing factors with respect to the public health effect of prohibiting a product, such as tobacco or menthol flavored cigarettes, that is used regularly by a large number of heavily addicted adults. Therefore, Congress determined that regulation of such products would require further research. The legislative history states:

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.<sup>172</sup>

---

<sup>169</sup> HR Report, at 38. Exhibit US-67.

<sup>170</sup> Scientific research, using conventional smoking-machine analysis, has found that clove cigarettes produce more nicotine, tar and carbon monoxide than conventional cigarettes. *See Clove Cigarette Smoking: Biochemical, Physiological, and Subjective Effects*, Exhibit US-44. Similarly, other scientific research has found that smoking clove cigarettes also produces higher levels of other potentially harmful constituents than regular cigarettes. *See Determination of eugenol, anethole, and coumarin in the mainstream cigarette smoke of Indonesian clove cigarettes*. Exhibit US-45. *Quantification of flavor-related compounds in the unburned contents of bidi and clove cigarettes*, Exhibit US-46.

<sup>171</sup> The findings of the FSPTCA state that “a consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.” FSPTCA Sec 2(2). Exhibit US-7.

<sup>172</sup> HR Report, at 38. Exhibit US-67.

135. Congress excluded tobacco- and menthol- flavored cigarettes from Section 907(a)(1)(A) solely for the reason that millions of adult users are addicted to them, and there is no current scientific basis upon which Congress could conclude that it would be appropriate for the public health to remove them. Section 907(a)(1)(A) – and the exceptions to it – are based on a scientific assessment of consumer use, and not on the basis of the national origin of the products that would be affected by the ban.

#### **4. Mandate to Study the Public Health Impact of Menthol in Cigarettes**

136. Congress recognized the unique nature of menthol-flavored cigarettes. As described above, menthol-flavored cigarettes for years have been marketed not only to youth but specifically to the African American community, and indeed are smoked in large numbers by both adults and youths.<sup>173</sup> Moreover, some studies have suggested that menthol flavored cigarettes might pose unique health risks to those who smoke them.<sup>174</sup>

137. FSPTCA section 907(e) expressly mandates that the FDA’s TPSAC further research regulation of menthol-flavored cigarettes and issue a report and recommendation on the issue of the impact of the use of menthol in cigarettes on the public health. Section 907(e) states in relevant part

Menthol Cigarettes --

(1) Referral, Considerations – Immediately upon establishment of the Tobacco Products Advisory Committee under section 917(a), the Secretary shall refer to the Committee for report and recommendation [...] 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.

138. Section 907(e) further instructs that the TPSAC shall address the following considerations: (1) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.<sup>175</sup> Section 907(e) also require the committee to consider the technical achievability of proposed standards and “other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant

---

<sup>173</sup> HR Report, at 38. Exhibit US-67.

<sup>174</sup> HR Report, at 38. Exhibit US-67.

<sup>175</sup> FSPTCA sec. 907(a)(3)(B)(i). Exhibit US-7. These considerations apply to all new product standards under Section 907(a)(1)(A).



demand for contraband or other tobacco products that do not meet the requirements of the chapter and the significance of such demand.”<sup>176</sup>

139. In compliance with the Act, the TPSAC was formed in March 2010 and will issue its report and recommendation with respect to the use of menthol in cigarettes by March 23, 2010. Consistent with the purpose and standards established in the FSPTCA, the review will consider approaches to minimizing the use of menthol-flavored cigarettes with a view to the relative benefits, risks and costs to the public health, as elaborated in the considerations listed above.

### **I. The United States’ Approach to Tobacco Regulation Is Consistent With Global Efforts**

140. The United States – like most countries in the world – recognizes the inherent dangers of tobacco and pursues a policy to minimize the harms of tobacco products wherever practicable, within such constraints as U.S. Constitutional free-speech protections on advertising and certain countervailing public health considerations associated with limiting or eliminating access to addictive products.<sup>177</sup>

141. The United States is one of 168 signatories to the World Health Organization Framework Convention on Tobacco Control (“WHO Tobacco Convention”). The FSPTCA’s focus on scientifically based measures to minimize the harms of tobacco (particularly by reducing youth smoking) is consistent with the approach embodied in the WHO Tobacco Convention.

142. The WHO Tobacco Convention emphasizes in its Preamble that the Parties to the Convention are “*determined* to give priority to their right to protect public health,” and “*deeply concerned* about the escalation of smoking and other forms of tobacco consumption by children and adolescents worldwide, particularly smoking at increasingly early ages.”<sup>178</sup>

143. Parties to the WHO Tobacco Convention also are “*determined* to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations,”<sup>179</sup> and recognize that tobacco control requires a multi-faceted approach focusing

---

<sup>176</sup> FSPTCA sec. 907(b). Exhibit US-7.

<sup>177</sup> For example, the United States Government prohibits the use of government funds to promote the sale or export of tobacco or tobacco products or to seek the removal of restrictions on marketing such products. P.L. 111-117, 123 Stat. 3151, sec. 510 (December 16, 2009). Exhibit US-68.

<sup>178</sup> World Health Organization, Framework Convention on Tobacco Control, 23 June 2003, Article 16, I.L.M. 518. Indonesia is not a signatory or Party to the Convention. Exhibit US-69.

<sup>179</sup> WHO Tobacco Convention, Preamble. Exhibit US-69.

on reducing supply and demand and other factors.<sup>180</sup> Section 907(a)(1)(A) is part of a broader architecture contained in the FSPTCA, which controls and restricts every aspect of tobacco products, from how they are manufactured to how they reach and are presented to consumers. No Party to the WHO Tobacco Convention – or any other country, as far as the United States is aware – has prohibited a tobacco product to which millions within its borders are addicted.

#### **IV. LEGAL ARGUMENT**

##### **A. Section 907(a)(1)(A) Is Not Inconsistent With the National Treatment Provisions Contained in the GATT 1994 or the TBT Agreement**

144. Indonesia argues that Section 907(a)(1)(A) is inconsistent with Article III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement based on a flawed analysis and insufficient evidence that Section 907(a)(1)(A) accords less favorable treatment to cigarettes imported from Indonesia than to cigarettes produced in the United States.

145. As an initial matter, we note that Indonesia first sets forth its TBT national treatment analysis,<sup>181</sup> (relying upon Appellate Body guidance in *EC – Asbestos*) and later states with respect to its GATT claim that “for the same reasons outlined above with respect to TBT Article 2.1, Section 907(a)(1)(A) is inconsistent with GATT Article III:4.”<sup>182</sup> However, for analytic clarity, the United States will begin with the GATT Article III:4 analysis, which has been more fully elaborated by previous Panels and the Appellate Body than TBT Article 2.1.

##### **B. Section 907(a)(1)(A) Is Not Inconsistent With GATT Article III:4**

###### **1. Introduction**

146. Section 907(a)(1)(A) prohibits cigarettes of any origin that contain an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, that is a characterizing flavor of the tobacco product or tobacco smoke. Section 907(a)(1)(A) is intended to eliminate the availability of type of cigarette used primarily by youths, often as a “starter cigarette.”<sup>183</sup>

147. The most credible evidence demonstrates that cigarettes with a characterizing flavor, other than tobacco or menthol (and including clove), overwhelmingly are smoked by youth and

---

<sup>180</sup> See, e.g., WHO Tobacco Convention. Part III, “Measures relating to the reduction of demand for tobacco,” and Part IV, “Measures relating to the reduction of supply of tobacco.” Exhibit US-69.

<sup>181</sup> Indonesia First Written Submission at paras 36-69.

<sup>182</sup> Indonesia First Written Submission at para 72.

<sup>183</sup> See section III.E(2) and (3).

are not smoked by adults in appreciable numbers.<sup>184</sup>

148. Banning clove cigarettes and other-flavored cigarettes does not present the same public health risk in the United States as banning regular or menthol cigarettes. Congress banned cigarettes with a characterizing flavor other than tobacco or menthol based on evidence that the benefits to the public health would be appreciable and the risks of potential harm to the public health would be negligible. Congress could not similarly conclude that the risks of potential harm to the public health of banning tobacco-flavored cigarettes or menthol cigarettes would be negligible. In particular, Congress specifically notes, the questions with respect to the effect on the public health of banning the menthol-flavored cigarettes are complex, and so far have not been fully addressed.<sup>185</sup>

149. The United States does not disagree with Indonesia’s general assertion that clove cigarettes are smoked by a small fraction of the population while menthol cigarettes are smoked in much larger numbers.<sup>186</sup> However, the relevant point with respect to Section 907(a)(1)(A) is that of the small amount of the population that smokes cloves, it is especially youth to whom they appeal. Additionally, while a small fraction of adults smoke clove cigarettes (and, therefore will not, on balance, be affected by the ban), a large number of adults smoke menthol cigarettes, both in terms of percentage of the population and in absolute numbers, and many cite them as their daily, regular cigarette.<sup>187</sup>

150. The public health effects of removing precipitously a cigarette which tens of millions of people smoke regularly have not been sufficiently evaluated to justify a ban.<sup>188</sup> Therefore, Section 907(a)(1)(A) does not ban tobacco- or menthol-flavored cigarettes. On the other hand, Congress has no evidentiary-based reason to exclude clove-flavored cigarettes from the Section 907(a)(1)(A) ban on cigarettes with a characterizing flavor.

## **2. GATT Article III:4**

151. Article III:4 of the GATT 1994 states in relevant part:

---

<sup>184</sup> Section III.F. Moreover, cigarettes with characterizing flavors other than tobacco or menthol are smoked as a “special occasion” or experimental cigarette, and therefore likely create a pleasurable association with tobacco that encourages further use. By contrast, tobacco- and menthol-flavored cigarettes are the regular, daily cigarette used by millions of American adults, most of whom smoke them daily.

<sup>185</sup> HR Report. Exhibit US-67.

<sup>186</sup> Indonesia First Written Submission at para 40.

<sup>187</sup> Indonesia First Written Submission at para 40.

<sup>188</sup> See section III.H.

The products of the territory of any [Member] imported into the territory of any other [Member] shall be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. 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 transport and not on the nationality of the product.

152. To meet its burden under GATT Article III:4, Indonesia must demonstrate (1) that imported and domestic products are “like;” (2) that the measures at issue is either a law, regulation, or requirement affecting their internal sale, offering for sale, purchase, transportation, distribution, or use; and (3) which provides to imported products a treatment less favorable than that accorded to like domestic products.<sup>189</sup>

153. Indonesia’s argument boils down to the proposition that GATT 1994 Article III:4 precludes the United States from banning a specific class of cigarettes including clove cigarettes unless it also bans domestically produced cigarettes sold in the United States, without exception. However, Indonesia fails to prove two of the three requirements for an Article III claim. First, Indonesia does not demonstrate that clove cigarettes are “like” domestically produced cigarettes (in particular tobacco and menthol cigarettes). Second, Indonesia fails to show that Section 907(a)(1)(A) accords less favorable treatment to clove cigarettes based on their national origin.

### **3. Clove Cigarettes Are Not “Like” Tobacco and Menthol Cigarettes**

154. Indonesia proposes that domestic cigarettes and clove cigarettes are “like” products with respect to Section 907(a)(1)(A). However, the analysis below will demonstrate that clove cigarettes are not in a competitive relationship with tobacco or menthol cigarettes and are not substitutable or interchangeable among retailers or consumers. Therefore, for purposes of Section 907(a)(1)(A), Indonesian clove cigarettes are not like U.S.-manufactured tobacco or menthol cigarettes.

155. The Appellate Body recognized in *EC – Asbestos* that the “‘general principle’ set forth in Article III:1 ‘informs’ the rest of Article III and ‘acts as a guide to understanding and interpreting the specific obligations contained’ in the other paragraphs of Article III.”<sup>190</sup> Article III:1 of the GATT 1994 states in relevant part that Members “recognize that internal taxes and other internal charges, and laws and regulations and requirements [...] should not be applied to imported or

---

<sup>189</sup> *Korea – Beef* (Panel) at 617.

<sup>190</sup> *EC – Asbestos (AB)*, para. 93, citing Appellate Body Report *Japan – Alcoholic Beverages*, fn 58 at 111.

domestic products so as to afford protection to domestic production.”<sup>191</sup>

156. The Appellate Body further noted in *EC – Asbestos* that the “general principle” expressed in Article III:1 “seeks to prevent Members from applying internal taxes and regulations in a manner which affects the competitive relationship, in the marketplace, *between the domestic and imported products involved*, so as to afford protection to the domestic production.”<sup>192</sup>

157. Panels have used at least four criteria to the extent that it is helpful in a determination of likeness: (1) the properties, nature and quality of the products; (2) end-uses of the products; (3) consumers’ tastes and habits in respect of the products; and (4) the international classification of the products for tariff purposes.<sup>193</sup> The Appellate Body noted in *EC – Asbestos* that these criteria provide a framework for analyzing likeness but are simply tools,<sup>194</sup> and that “a determination of ‘likeness’ under Article III:4 is, fundamentally, a determination about the nature and extent of a competitive relationship between and among products.”<sup>195</sup>

158. The United States generally agrees with Indonesia’s recognition that there is no one precise definition of “like product,” and “the term must be interpreted in light of the context” and “the object and purpose of the covered agreement in which the provision appears.”<sup>196</sup>

159. The United States also notes that Section 907(a)(1)(A) makes distinctions among a group of broadly similar products – cigarettes – based on factors relevant to the legitimate objective of protecting the public health. Accordingly, a “likeness” determination – in addition to focusing on the competitive relationship of the products – will need carefully to parse the significance of traits that are generally shared among all cigarettes and traits that are significant with respect to the public health provision at issue.<sup>197</sup>

---

<sup>191</sup> *EC – Asbestos (AB)*, para. 98.

<sup>192</sup> *EC – Asbestos (AB)*, para. 98.

<sup>193</sup> *EC – Asbestos (AB)*, para. 101.

<sup>194</sup> *EC – Asbestos (AB)*, para. 101.

<sup>195</sup> *EC – Asbestos (AB)*, paras. 99.

<sup>196</sup> *EC – Asbestos (AB)*, para. 88. Indonesia First Written Submission, para. 48.

<sup>197</sup> Along these lines, Indonesia’s reliance upon the finding in *Dominican Republic – Cigarettes* of “likeness” between cigarettes produced in the Dominican Republic and in Honduras is misplaced. To begin, the Parties agreed that “likeness” was not at issue in the disputes, which concerned the application of a bond requirement to imported cigarettes. In addition, the Panel noted that the cigarettes “compete against each other and are interchangeable for consumers.” *Dominican Republic- Cigarettes (Panel)*, para. 7.165. It is not the case here that Indonesian clove cigarettes compete against or are interchangeable with domestically produced tobacco or menthol cigarettes.

**(a) Properties, Nature and Quality**

160. Consistent with the Appellate Body’s consideration that a determination of “likeness” fundamentally concerns the competitive relationship of products, the Appellate Body further reasons that, “in particular, panels must examine those physical properties of products that are likely to influence the competitive relationship between products in the marketplace.”<sup>198</sup>

161. In support of its claim that “clove cigarettes have the same physical characteristics as domestically produced cigarettes, especially menthol cigarettes,” Indonesia notes only a few generic characteristics, and ignores the characteristics most relevant to the marketplace. For example, Indonesia notes that domestic and Indonesian cigarettes “contain cured and blended tobacco in a paper wrapper with a filter,” and other flavorings.<sup>199</sup> However, an examination of cloves’ physical properties reveals that clove cigarettes are in fact different from other cigarettes in their physical composition.

**i. Clove Cigarettes Have Distinct Physical Characteristics**

162. The physical composition of clove cigarettes is different than tobacco and menthol cigarettes. Clove buds are dried flower buds harvested from clove trees. They impart a sweet and spicy flavor and aroma and are often used in baked goods, candies, and beverages.<sup>200</sup>

163. Clove is a prominent ingredient in a clove cigarette. Clove cigarettes typically contain 60% tobacco and 40% clove buds and cocoa, which adds the characteristic flavor and quality to the smoke.<sup>201</sup> Tobacco and menthol cigarettes do not contain significant quantities of food ingredient.

164. In addition, unlike other cigarettes, clove cigarettes contain significant quantities of eugenol, which creates an anesthetic and numbing effect reportedly appealing to new smokers.<sup>202</sup> As discussed, eugenol, a natural constituent of clove oil, is an active ingredient distinguishing

---

<sup>198</sup> *EC – Asbestos (AB)* para. 114.

<sup>199</sup> Indonesia First Written Submission, para. 54.

<sup>200</sup> Polzin, *et al.*, “Determination of eugenol, anethole, and coumarin in the mainstream cigarette smoke of Indonesian clove cigarettes,” *Food & Chemical Toxicology* 45(10): 1948-49. Exhibit US-45.

<sup>201</sup> See section III.E(2).

<sup>202</sup> See section III.E(2). See *Clove Cigarettes*, at 537 (Clove cigarettes are sweetly aromatic, and some numbing of the mouth occurs. The effect is to remove much of the unpleasantness of cigarette smoking for new smokers. They have been called ‘trainer’ cigarettes.”). Exhibit US-41.

clove cigarettes from regular and menthol cigarettes.<sup>203</sup> Clove buds contribute to generating high levels of eugenol in the smoke. A study performed by the Center for Disease Control and Prevention in 2007 examined 33 brands of Indonesian clove cigarettes, and found that all contained levels of eugenol ranging from 2.49-37.9 mg/cigarette.<sup>204</sup>

165. Clove cigarettes also contain a special, proprietary “sauce” that is credited with some of their appeal.<sup>205</sup> As Pt Djarum explained, “It is not just the cloves that make kretek special, but also the secret sauce that adds to its enjoyment. Blending the unique taste of tobacco, fruit and herb extracts, and other natural flavorings, some say the kretek sauce recipe is more closely guarded than that of Coca Cola. [...] All adds to a *richer and fruity* taste, *sweet-scented* aroma and *pleasant* aftertaste than any regular cigarettes, and well-appreciated by kretek connoisseurs.”<sup>206</sup> The makers of clove cigarettes introduce these physically different flavoring additives for the purpose of differentiating clove cigarettes from other cigarettes, and they have succeeded in doing so. In short, clove cigarettes taste different from other cigarettes.

166. Clove cigarettes also contain the harmful chemical coumarin, which is no longer found in most cigarettes. Analysis has identified levels of coumarin, a chemical linked to hepatotoxicity in humans, in flavor compounds in clove cigarette casings and mainstream smoke emissions.<sup>207</sup> In one study, 64% of clove cigarette brands tested contained coumarin at levels between 9.2 and 215µg per cigarette.<sup>208</sup> By contrast, only a single brand of 68 conventional cigarettes available in the United States had detectable levels of coumarin.<sup>209</sup> Coumarin is banned as a food-flavoring

---

<sup>203</sup> World Health Organization, International Agency for Research on Cancer. Tobacco smoke and Involuntary Smoking. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 83. <http://monographs.iarc.fr/ENG/Monographs/vol83/index.php> Exhibit US-70.

<sup>204</sup> Polzin GM, Stanfill SB, Brown CR, Ashley DL, Watson CH. *Determination of eugenol, anethole, and coumarin the mainstream cigarette smoke of Indonesian clove cigarettes*. Food and Chemical Toxicology 2007;45(10):1948-1953. Exhibit US-45.

<sup>205</sup> *Determination of eugenol, anethole, and coumarin the mainstream cigarette smoke of Indonesian clove cigarettes*, Exhibit US-45.

<sup>206</sup> Demirtas, “Djarum Cigarettes & Cigars,” <http://www.demirtas.com.tr/Djarum.htm> (emphasis added), Exhibit US-39.

<sup>207</sup> World Health Organization, International Agency for Research on Cancer. Tobacco smoke and Involuntary Smoking. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 83. Exhibit US-70.

<sup>208</sup> Stanfill SB, Brown CR, Yan XJ, Watson CH, Ashley DL. Quantification of flavor-related compounds in the unburned contents of bidi and clove cigarettes, Exhibit US-46.

<sup>209</sup> Stanfill SB, Ashley DL. Solid phase microextraction of alkenylbenzenes and other flavor-related compounds from tobacco for analysis by selected ion monitoring gas chromatography-mass spectrometry. *A J Chromatogr* . 1999;858(1):79-89. Exhibit US-71.

agent in the United States, and is currently listed by the FDA among “substances Generally Prohibited from Direct Addition or Use as Human Food.”<sup>210</sup>

167. Clove cigarettes also contain a range of other flavor compounds not commonly found in tobacco or menthol cigarettes. The Centers for Disease Control and Prevention tested 17 regular tobacco cigarettes, 18 menthol cigarette brands and 13 clove cigarettes for the presence and quantity of 18 flavor compounds known to be common in cigarettes.<sup>211</sup> None of the regular tobacco cigarette products contained detectable levels of any of the 18 flavor compounds. All of the menthol cigarette products contained menthol but none of the other 17 flavor compounds. Five of the 18 flavor compounds were present in all 13 of the clove cigarettes. Coumarin was present in 12 of the 13 clove cigarettes tested. All 13 of the clove cigarettes contained between 7 and 13 of the 18 flavor compounds.

168. The unique physical properties in clove cigarettes create a different physical experience for smokers than the experience created by other cigarettes such as tobacco or menthol cigarettes. For example, studies indicate that smokers inhale clove cigarettes more deeply, increasing the amount of nicotine extracted from each cigarette, making it possible for the smoker to achieve comparable blood concentrations of nicotine, even though clove cigarettes contain less nicotine per cigarette than do conventional brands.<sup>212</sup> Additionally, clove cigarettes have been shown to take more puffs and a longer amount of time to smoke.<sup>213</sup>

169. Because of the unique physical properties of cloves, and the resulting sweet taste and special physical experience, users of clove cigarettes in the United States associate cloves with such feelings of “indulgence” and “special occasions,” and, therefore, use clove cigarettes specifically to invoke the experiences derived from those physical properties.<sup>214</sup> Clove cigarettes are also known to be attractive to uninitiated smokers for this reason.<sup>215</sup>

170. The physical properties of cloves (the “sauce” flavoring, anesthetic effect of the eugenol and the spicy taste of the clove itself) influence the competitive relationship of clove cigarettes and other cigarettes – that is, the physical properties influence how smokers choose to use them

---

<sup>210</sup> Coumarin has not been banned as an additive in cigarettes.

<sup>211</sup> Stanfill S, Duncan B, Yan X, Richter P, Watson CH. Levels of 18 flavor analytes present in non-mentholated, mentholated and clove cigarettes products. 2010. Exhibit US-72.

<sup>212</sup> *Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes*, Exhibit US-42; *see also CDC Article Regarding Epidemiology and Illnesses Possibly Associated with Cloves* (“Exposure to tar, nicotine and carbon monoxide is higher from clove cigarettes than from regular American cigarettes.”), Exhibit US-47.

<sup>213</sup> *Clove cigarette smoking: biochemical, physiological, and subjective effects*, Exhibit US-44.

<sup>214</sup> See section III.E(2) and III.F.

<sup>215</sup> See section III.F.



compared to other cigarettes. As acknowledged even PT Djarum, clove cigarettes do not compete with so-called “conventional cigarettes” (*i.e.*, tobacco and menthol) but rather are used in addition to those cigarettes.<sup>216</sup> They also are used by new smokers unaccustomed to the harsher tobacco taste of other cigarettes.<sup>217</sup>

## **ii. The Physical Characteristics of Menthol Cigarettes Are Not Like Clove Cigarettes**

171. Menthol and the clove buds contained in clove cigarettes are completely different physical products. Menthol, which is an aromatic oil that is synthesized or derived from peppermint plants, is not as physically prominent in a menthol-flavored cigarette. In contrast to clove, which comprises nearly half of clove cigarettes by weight, menthol comprises less than 1% of a menthol cigarette. Menthol levels in brands marketed as menthol cigarettes range between 0.15-0.58 mg/cigarette.<sup>218</sup> The presence of eugenol in clove cigarettes is at levels of 20-70 times higher than those of menthol in menthol cigarettes. In addition, menthol cigarettes do not tend to contain coumarin or an array of other flavoring compounds typically found in clove cigarettes.<sup>219</sup>

172. Just as the unique taste and physical properties of cloves influence the choices of U.S. consumers, so the unique taste and physical properties of menthol influence consumer choices. For example, existing research and data show that those who smoke menthol cigarettes tend to use them as their main brand.<sup>220</sup> Whereas clove cigarettes smokers enjoy the unique experience of cloves as a starter cigarette or “from time to time,” smokers of menthol cigarettes tend to choose menthols as their daily cigarette.

## **iii. Indonesia Is Incorrect That Clove Is a Flavoring Like Other Flavor Additives**

---

<sup>216</sup> See section III.E(2).

<sup>217</sup> PT DJ Darum observed in March 2009 (6 months before Section 907(a)(1)(A) went into effect) that “overseas kretek smokers [e.g., those in the United States] are more likely to reserve their clove cigarettes for special occasions. Such smokers seek to indulge themselves once and a while, to savour a unique experience from time to time.” PT DJARUM, “Kretek Today,” <http://www.djarum.co.id/en>, accessed March 24, 2009. See also <http://www.djarum.com/?mod=historyofkretek>.

<sup>218</sup> *Determination of eugenol, anethole, and coumarin the mainstream cigarette smoke of Indonesian clove cigarettes*, Exhibit US-45.

<sup>219</sup> *Levels of 18 flavor analytes present in non-mentholated, mentholated and clove cigarettes products*, 2010, Exhibit US-72

<sup>220</sup> Kreslake, JM, et al., “The Menthol Smoker: Tobacco industry research on consumer sensory perception of menthol cigarettes and its role in smoking behavior,” *Nicotine & Tobacco Research* 10(4), April 2008. Exhibit US-73.

173. Indonesia makes much of the fact that many “regular” domestic cigarettes contain additives such as sugar or vanilla.<sup>221</sup> From this, Indonesia makes the unsupportable leap to the conclusion that “regular” cigarettes are like products to cigarettes with “characterizing flavors.”<sup>222</sup>

174. “Regular” tobacco cigarettes, as Indonesia notes, consist of cured and blended tobacco. Domestic mentholated cigarettes also contain 1% menthol. Consistent with clove-manufacturers’ claims about the significance of the flavors contained in clove cigarettes, tests conducted to detect 18 commonly-used flavor compounds determined that regular cigarettes and menthol cigarettes – unlike clove cigarettes – did not contain any of the 18 flavor compounds (other than menthol in menthol cigarettes).<sup>223</sup>

175. Moreover, evidence shows that – contrary to Indonesia’s claim that there is nothing different about clove flavor – consumers differentiate clove cigarettes because of their unique flavor. Clove cigarettes are marketed for the appeal of their unique flavor, and consumers report that they smoke cloves for the unique flavor. Consumers consider the taste and aroma created by the physical property of cloves as different and more pleasing.<sup>224</sup> For example, subjects in a 2003 test reported that they liked the taste of clove cigarettes more than their usual brand and rated it as “significantly different” from their own brand.<sup>225</sup>

176. Indonesia does not consider the many physical differences between clove cigarettes and other cigarettes – menthol cigarettes, in particular. Accordingly, Indonesia fails to meet its burden of demonstrating that clove and tobacco and menthol cigarettes are “like” in terms of physical properties. In fact, the physical properties are distinct, and these distinctions are directly related to consumer choices and the competitive relationship among the products.

177. The Appellate Body noted that when the physical properties of products are dissimilar, a “high burden is imposed on a complaining Member to establish that, despite the pronounced physical differences, there is a competitive relationship between the products such that, *all* the evidence, taken together, demonstrates that the products are ‘like.’”<sup>226</sup> However, despite this

---

<sup>221</sup> Indonesia First Written Submission, paras. 6, 54.

<sup>222</sup> Indonesia First Written Submission, paras. 6, 54.

<sup>223</sup> Stanfill S, Duncan B, Yan X, Richter P, Watson CH. Levels of 18 flavor analytes present in non-mentholated, mentholated and clove cigarettes products. 2010. Exhibit US-72.

<sup>224</sup> See sections III.E(2) and III.F.

<sup>225</sup> *Clove cigarette smoking: biochemical, physiological, and subjective effects*, at 742. Exhibit US-44.

<sup>226</sup> *EC – Asbestos (AB)*, paras. 118, 136 (emphasis in original and added in part).

heightened burden, Indonesia presents even less evidence of “likeness” with respect to the other factors generally used to identify likeness.

**(b) End-Uses**

178. Panels have considered that the “extent to which the products are capable of serving the same or similar end-uses” is relevant to the determination of likeness.<sup>227</sup> The Appellate Body provided further guidance that it is necessary to form a “complete picture” of the “various end-uses of a product.”<sup>228</sup>

179. Contrary to Indonesia’s one-sentence conclusion on end-use, cigarettes actually have a number of end-uses and are not just used to “smoke tobacco.”<sup>229</sup> Cigarettes have at least two other end-uses in the United States, which clove, menthol and tobacco cigarettes serve in differing degrees.

180. Cigarettes serve the end-use of satisfying an addiction to nicotine. Notably, evidence show that most of the some 46 million Americans who regularly smoke, the vast majority smoke tobacco or menthol cigarettes.<sup>230</sup>

181. Cigarettes also serve the end-use of creating a pleasurable experience associated with the taste of the cigarette and the aroma of the smoke. Evidence suggests that clove cigarettes and other cigarettes with characterizing flavors, in particular, serve this end use in the United States, primarily among youths. For example, as noted above, clove cigarettes involve an “indulgent” taste that is associated with special occasions and is enticing for experimental use. Similarly, Phillip Morris recognized in 1992 that flavored cigarettes appeal uniquely to children because of the pleasant aroma and aftertaste, which contributed to the enjoyment, excitement, and curiosity factor of the cigarettes.<sup>231</sup>

**(c) Consumer Habits and Tastes**

182. The Appellate Body emphasized that where, as here, physical properties of the products are very different, an examination of evidence relating to consumers’ tastes and habits is

---

<sup>227</sup> *EC – Asbestos (AB)*, para. 101.

<sup>228</sup> *EC – Asbestos (AB)*, para. 119.

<sup>229</sup> Indonesia First Written Submission, para. 59.

<sup>230</sup> See section III.A.

<sup>231</sup> *New Cigarette Brands with Flavors that Appeal to Youth*, at 1603, Exhibit US-40.

indispensable to determining “likeness.”<sup>232</sup> The heart of this analysis is whether products are “interchangeable”<sup>233</sup> or “substitutable”<sup>234</sup> in the view of consumers, demonstrating a competitive relationship.

183. Consumer habits and preferences are a key factor in determining whether different types of cigarettes are like products. Indeed, Indonesia acknowledges this fact itself, when finally it concludes that cigarettes that appeal to youth smokers may “present a specific health risk by encouraging new, young smokers,” and therefore need not be considered “like” other cigarettes. As a factual matter, Indonesia disputes that clove cigarettes fall into the category of flavored cigarettes that appeal to youth smokers, though Indonesia’s evidence on that point is unreliable and unpersuasive (see section III.F). However, Indonesia nevertheless concedes to the legal point that consumer habits and preferences are a distinguishing factor among cigarettes, and that, in fact, all cigarettes need not like products.

184. Unlike cases where panels have found that consumers perceive and use products as interchangeable and substitutable, in this case, consumers clearly differentiate between products. Indonesia has presented no evidence to demonstrate that clove cigarettes seek to compete with tobacco or menthol cigarettes, or that consumers view them as substitutable.

185. Clove cigarettes are marketed, sold and used as a “special occasion” tobacco product while tobacco and menthol cigarettes are marketed, sold and used as a daily, regular cigarette.<sup>235</sup> Clove cigarettes are smoked overwhelmingly by young people, who tend to be novice smokers.<sup>236</sup> Tobacco and menthol cigarettes are used regularly by a large population of young people, but especially adults, who smoke them regularly.<sup>237</sup>

186. Clove cigarettes were not competing for the “regular use” market.<sup>238</sup> In fact, as Indonesia acknowledges,<sup>239</sup> 75% of smokers of tobacco and menthol cigarettes also smoke clove cigarettes

---

<sup>232</sup> *EC – Asbestos (AB)*, para. 139.

<sup>233</sup> *Dominican Republic – Cigarettes (Panel)*, para. 7.165.

<sup>234</sup> *Mexico – Beverage (Panel)*, para. 8.103 (noting that the products are “near perfect substitutes”) and para. 8.34 (finding that there does not seem to be a conspicuous difference in taste between the two products, and that any difference is even less noticeable with respect to the particular end-use).

<sup>235</sup> See sections III.E(2) and III.F.

<sup>236</sup> See sections III.E(2) and III.F.

<sup>237</sup> See section III.F.

<sup>238</sup> See sections III.E(2) and III.F. .

<sup>239</sup> Indonesia First Written Submission, para. 60.

on occasion, evidencing the point that rather than competition among products there is in fact an overlap and likely symbiosis. Clove cigarettes not only attract new users to tobacco, but are used as a supplemental, special occasion cigarette among those who already smoke.

187. Indonesia asserts, but has provided no evidence to demonstrate, that clove cigarettes compete with tobacco or menthol cigarettes for access to channels of distribution, shelf space or market share.<sup>240</sup>

188. Existing evidence with respect to consumer tastes and habits suggests that clove cigarettes are used “like” the other flavors prohibited under Section 907(a)(1)(A). Clove cigarettes – like chocolate or “Midnight Madness” or “Mandalay Lime” – are chosen almost exclusively by youths, experimentally or for “special occasions.”<sup>241</sup> As such, they have the effect of making tobacco seem appealing, especially to new users.<sup>242</sup> Such evidence suggests that the relevant competitive market for clove cigarettes was among the cigarettes which also were banned under section 907(a)(1)(A).

189. Indonesia does not attempt to prove that Indonesian clove cigarettes and regular or menthol cigarettes are viewed as “interchangeable” in the market. Instead, Indonesia presents unreliable data to suggest that clove cigarettes have a pattern of use similar to tobacco or menthol cigarettes, just on a smaller scale.<sup>243</sup> As explained in section III.F, these results cannot be relied upon. It is simply not the case, as Indonesia submits, that clove cigarettes are smoked primarily by adults, as are tobacco and menthol cigarettes. Moreover – and revealingly – Indonesia does not dispute the key fact that clove cigarettes are smoked by an insignificant fraction of adults.

#### **(d) International Tariff Classification**

190. The United States has no comment on Indonesia’s statement that clove cigarettes and domestically produced cigarettes have the same international tariff classification, except to note that Appellate Body emphasized that tariff classification, on its own, cannot be decisive.<sup>244</sup>

---

<sup>240</sup> Indonesia First Written Submission, para. 60. In fact, evidence shows that clove cigarettes primarily are sold in tobacco shops, head shops and other specialty stores, whereas tobacco and menthol cigarettes are sold in regular convenience stores and gas stations and other common locations. Contrary to Indonesia’s assertion, there is no evidence that clove cigarettes have sought to compete with domestic cigarettes for channels of distribution or shelf space, and to the contrary, embrace and promote themselves as “specialty” cigarettes sold largely in specialty stores. See sections III.E(2) and III.F.

<sup>241</sup> See sections III.E(2) and III.F.

<sup>242</sup> See sections III.E(2) and III.F.

<sup>243</sup> Indonesia First Written Submission, para. 62.

<sup>244</sup> *EC – Asbestos (AB)*, para. 119.

191. In addition, the United States submits that the fiscal treatment of two different products should have very little weight in the “like product” analysis when the domestic measure under consideration is adopted not for fiscal purposes, but in order to protect human health.<sup>245</sup>

192. To the extent the fiscal treatment of various types of cigarettes is relevant, the United States notes that Indonesia apparently does not treat clove cigarettes “like” imported tobacco or menthol cigarettes for domestic tax purposes. In particular, it appears that Indonesia taxes machine-made, domestic clove cigarettes at a lower rate than it taxes other types of machine-made cigarettes.<sup>246</sup>

193. Thus, to the extent that tax treatment is relevant, it appears that Indonesia does not treat domestic clove cigarettes as “like products” to imported tobacco or menthol cigarettes.

#### (e) Conclusion on Like Product

194. Indonesia has failed to meet its burden to prove that clove cigarettes are “like” tobacco and menthol cigarettes. In fact, aside from a few general characteristics of all cigarettes (such as the fact that they are rolled in paper and smoked), available credible evidence shows that clove cigarettes are not like domestically produced tobacco or menthol cigarettes.

195. As noted, the “four factors” applied above are considered by panels to the extent that they aid in a determination of likeness. In this case, the factors provide a framework to arrive at the crucial conclusions that (1) clove cigarettes are not in a competitive relationship with tobacco or menthol cigarettes, and (2) clove cigarettes are not interchangeable or substitutable with tobacco or menthol cigarettes. They are not like products.

#### 4. Section 907(a)(1)(A) Does Not Afford Less Favorable Treatment to

---

<sup>245</sup> For this reason, the cases cited by Indonesia for the notion that all cigarettes are “like” products do not apply here. Indonesia First Written Submission, paras. 51, 52. The panels in *Dominican Republic – Cigarettes* and *Thailand – Cigarettes* determined the domestic and imported cigarettes at issue were “like” for purposes of the tax measures at issue in the disputes. *Dominican Republic – Cigarettes (Panel)*, para. 7.164 and *Thailand – Cigarettes (Panel)*, para. 6. A like product analysis with respect to a regulatory measure that distinguishes among cigarettes for purposes of protecting the public health inevitably will involve different factors, as explained here.

<sup>246</sup> Indonesia’s tax system appears to differentiate between machine-produced kreteks (“SKM” in section 1) and machine-produced “white” cigarettes (“SPM” in section 2), though not between the hand-produced versions of each. See Ministry of Finance regulations number 181/PMK.011/2009, pp. 12. Exhibit US-74. The column on the far right is the tax per stick or gram on categories of cigarettes. There appears to be no excise tax on machine produced kreteks with a retail price of less than Rp. 600 per stick or gram in production category I or less than Rp. 374 in production category II, while the minimum retail price subject to tax for machine-produced white cigarettes is a much lower Rp. 375 for production category I or Rp. 217 for production category II. The United States further notes that under Indonesia’s Article III analysis, Indonesia’s cigarette taxation scheme would seem to raise serious questions about whether Indonesia treats imported regular cigarettes less favorably than Indonesia’s domestic clove cigarettes. Exhibit US-74.

### Clove Cigarettes Based on Origin

196. A measure violates the provisions of GATT III:4 if it accords less favorable treatment to a imported product than to a like domestic product based on national origin. Even aside from the fact that clove cigarettes are not like products to tobacco and menthol cigarettes, Indonesia has not met its burden to demonstrate that clove cigarettes are accorded less favorable treatment based on their national origin. Section 907(a)(1)(A) bans cigarettes with a characterizing flavor other than tobacco or menthol without respect to the origin of the cigarette, based on valid public health considerations.

197. It is important to recall that the question of “less favorable treatment” 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 measures,”<sup>247</sup> 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.” In the context of Article III:4, this general principle supports that Article III:4 should not be interpreted to prohibit measures that may result in some detrimental effect on imported products as compared to some like domestic products; instead, what Article III:4 prohibits are measures that accord less favorable treatment to imported products as compared to like domestic products based on origin.

198. In particular, Article III does not forbid Members from making regulatory distinctions between different products that may fall within a single “like product” class for Article III purposes.<sup>248</sup> Rather, Article III forbids Members from according less favorable treatment – on a *de jure* or *de facto* basis – to imported products as compared to domestic products.<sup>249</sup>

---

<sup>247</sup> *EC – Asbestos (AB)* para. 97.

<sup>248</sup> *EC – Asbestos (AB)*, para. 100 (“[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* products “less favorable treatment” than that accorded to the group of “like” *domestic* products.”).

<sup>249</sup> Where the Appellate Body has determined that like imported and domestic products have been treated differently based on national origin, it applies a second analysis to determine whether such different treatment accords *less favorable treatment* to the imported product. However, the Panel in this case need not reach such an analysis, as Section 907(a)(1)(A) does not accord different treatment based on origin. See *Korea – Beef (AB)*, para. 135. The Appellate Body in *Korea – Beef* noted that “We observe, [...] that Article III:4 requires only that a measure accord treatment to imported products that is ‘no less favorable’ than that accorded to like domestic products. A measure that provides treatment to imported products that is *different* from that accorded to like domestic products is not necessarily inconsistent with Article III:4, as long as the treatment provided by the measure is ‘no less favorable.’” *Korea – Beef (AB)*, para. 135. The Appellate Body in *Korea – Beef* initially found that the Korean measure at issue provided different treatment to imported and domestic products by requiring them to be distributed through separate distribution channels. After the initial finding of different treatment, the Appellate Body turned to examine whether this different treatment meant that imported products were treated less favorably based on the national origin of the product. The Appellate Body concluded that because the Korean measure itself imposed on retailers the “necessity of making a choice” between domestic and imported beef, it limited the marketing opportunities for imported beef, and thereby modified the conditions of competition to the detriment of this product.

**(a) Section 907(a)(1)(A) Is Facially Neutral With Respect to Domestic and Imported Cigarettes**

199. As an initial matter, Indonesia does not appear to argue that Section 907(a)(1)(A) on its face accords different treatment to imported products than it does to like domestic products based on origin. The ban on cigarettes with characterizing flavors other than tobacco or menthol applies equally to all cigarettes sold in the United States, regardless of where they are produced. Section 907(a)(1)(A) on its face is “origin-neutral.” Indonesia does not appear to dispute this fact.

200. As such, the measure at issue here is different than the measure in, for instance, *Korea – Beef*, where the regulation on its face differentiated between domestic and imported products. In that case, after finding different treatment based on origin, the Appellate Body turned to the question of whether the different treatment based on origin was, in fact, less favorable.<sup>250</sup>

201. In this case, the measure at issue is facially neutral, and it is Indonesia’s burden to prove that, as applied, the measure discriminates between Indonesian and domestic cigarettes based on origin and accords less favorable treatment to imported products as compared to domestic products.

**(b) Section 907(a)(1)(A) is Not *De Facto* Discrimination Based on National Origin**

202. Indonesia has not met its burden to prove *de facto* discrimination. Indonesia asserts without analysis that “there is no question that a ban on one product but not other like products creates unequal conditions of competition and is ‘less favorable’ treatment”<sup>251</sup> and that “a ban on clove cigarettes but not menthol or tobacco cigarettes creates unequal conditions of competition in the U.S. market and is, accordingly, ‘less favorable’ treatment.”<sup>252</sup> Indonesia does not, however, demonstrate that the allegedly different treatment is based on the national origin of clove cigarettes.

---

*Korea – Beef (AB)*, paras. 144-146.

<sup>250</sup> *Korea – Beef (AB)*, paras. 144-146. Likewise, the panel in *Thailand – Cigarettes* determined that if the tax measure, which facially discriminated between domestic and imported cigarettes, were mandatory and not discretionary, it would constitute “less favorable treatment” based on national origin (because the legislation did not mandate that the measure be applied, the panel did not find it to be discriminatory). *Thailand – Cigarettes (Panel)*, para. 84. In this case, however, different treatment accorded to clove cigarettes and tobacco and menthol cigarettes is not based on national origin.

<sup>251</sup> Indonesia First Written Submission, para. 67

<sup>252</sup> Indonesia First Written Submission, para. 68.



203. Moreover, Indonesia does not clarify *which* products it claims are subject to different treatment. In its First Written Submission, Indonesia argues that clove cigarettes are “like” domestically produced cigarettes, without exception.<sup>253</sup> It therefore would appear to be Indonesia’s position that a U.S. ban on cigarettes with a characterizing flavor that includes clove would discriminate based on origin, unless the United States also banned *every* domestically produced cigarette, flavored or otherwise.<sup>254</sup>

204. Indonesia’s insistence that Section 907(a)(1)(A) violates GATT III:4 because it draws a distinction between clove cigarettes and, apparently, any domestic cigarettes is inconsistent with the Appellate Body interpretation of “less favorable treatment” – even if were to be determined that clove cigarettes and all domestic cigarettes are “like” products. The Appellate Body recognizes that a Member may draw distinctions between products determined to be “like” without affording protection to domestic production or according less favorable treatment to imported products.<sup>255</sup>

205. Measures that do not treat products differently based on origin, and for which the effects resulting from the measure are not a result of the origin of the product, are not measures that afford protection to domestic production.

206. For example, the Appellate Body has found that where, such as here, a measure applies equally to domestic and imported products and there is a detrimental effect on a given imported product, the measure is not necessarily inconsistent with Article III:4 if that detrimental effect is unrelated to the foreign origin of the product and instead due to some other factor, such as the composition of the market.<sup>256</sup> In *Dominican Republic – Cigarettes*, the Appellate Body noted

---

<sup>253</sup> Indonesia First Written Submission, paras. 48-65 (for example, heading A.1.c states “Clove cigarettes are “like” domestically produced cigarettes in the United States, especially menthol cigarettes.”).

<sup>254</sup> Alternatively, Indonesia may be arguing that clove cigarettes are “like” tobacco and menthol cigarettes and are not “like” the other cigarettes with a characterizing flavor that are effected by the ban. *See* Indonesia First Written Submission para. 63 (suggesting that, based on consumer habits, “‘regular,’ menthol, and clove cigarettes should be considered ‘like’ products” and need not be considered “like” other additives banned under Section 907(a)(1)(A) which could fairly be called “candy” flavors). However, Indonesia does not make this argument anywhere in its submission unequivocally or with factual support – in fact nearly all of Indonesia’s evidence purports erroneously to demonstrate that all cigarettes are “like” products. Moreover, as demonstrated above, this “like” product analysis is factually wrong, as clove cigarettes overwhelmingly are “like” exotic flavored cigarettes and not tobacco or menthol cigarettes, especially with respect to consumer habits.

<sup>255</sup> *EC – Asbestos (AB)*, para. 100.

<sup>256</sup> One of the only WTO reports where a WTO panel or Appellate Body has found distinct treatment on a *de facto* rather than a *de jure* basis is *Mexico – Soft Drinks*. In that dispute, the panel found that a Mexican measure that imposed a 20 percent tax on the use of non-cane sugar sweeteners (such as high fructose corn syrup) discriminated against imports because the sweeteners produced in Mexico at the time the tax was adopted consisted overwhelmingly of cane sugar, whereas almost 100 percent of imported sweeteners consisted of high fructose corn syrup. Thus, in applying a 20 percent tax on the use of non-cane sugar sweeteners that it did not impose on the use

that “the existence of a detrimental effect on a given imported product resulting from a measure does not necessarily imply that this measure accords less favourable treatment to imports if the detrimental effect is explained by factors or circumstances unrelated to the foreign origin of the product, such as the market share of the importer in this case.”<sup>257</sup> Accordingly, the Appellate Body found that a Dominican Republic measure did not accord less favorable treatment to imports even though it imposed higher per-unit costs on these products than domestic like products, because these higher per-unit costs were related to existing market conditions that had nothing to do with origin.

207. Similarly, the Appellate Body’s approach in *Chile – Alcoholic Beverages* is instructive on this point. In *Chile – Alcoholic Beverages*, a tax measure that was not facially discriminatory in fact imposed a higher rate to an imported product. However, the different treatment accorded by the tax was not enough in itself to constitute *de facto* discrimination, unless the different treatment was based on national origin.<sup>258</sup> Following its approach in *Japan – Alcoholic Beverages*, the Appellate Body examined the design, architecture and structure of the measure at issue, seeking to determine whether the measure was applied “so as to afford protection to domestic production.”<sup>259</sup> The Appellate Body concluded that the measure in question was “anomalous” and inconsistent with respect to the Chilean tax system, and therefore constituted an instance of *de facto* discrimination.<sup>260</sup>

208. Unlike in *Chile – Alcoholic Beverages*, where the Appellate found an “absence of countervailing explanations from Chile,”<sup>261</sup> there is in this case a legitimate countervailing explanation for the different treatment under Section 907(a)(1)(A) of tobacco and menthol cigarettes as compared to clove cigarettes.

209. In this case, the application of 907(a)(1)(A) is entirely consistent with the object and purpose of the FPSTCA and the approach of the United States to tobacco regulation, in general. An Indonesian product is adversely effected under Section 907(a)(1)(A) not as a result of origin-based discrimination, but because U.S. health authorities legitimately determined that clove cigarettes fall into a category of cigarettes that should be banned from the U.S. market for the protection of the public health. Section 907(a)(1)(A) distinguishes among cigarettes as

---

of cane sugar, Mexico was in practice singling out imported sweeteners and beverages containing them for higher taxation.

<sup>257</sup> *Dominican Republic – Cigarettes (AB)*, para. 96.

<sup>258</sup> *Chile – Alcoholic Beverages*, paras. 56-57, 71.

<sup>259</sup> *Chile Alcoholic Beverages (AB)*, paras. 56-71.

<sup>260</sup> *Chile Alcoholic Beverages (AB)*, para. 65.

<sup>261</sup> *Chile Alcoholic Beverages (AB)*, para. 71.

appropriate for the public health, and not based on the national origin of the products. Tobacco- and menthol-flavored cigarettes are not covered under Section 907(a)(1)(A) because a ban on such products would involve countervailing public health concerns.

210. Section 907(a)(1)(A) also does not afford protection to domestic production. Section 907(a)(1)(A) applies to a wide range U.S.-made cigarettes that were headed for the U.S. market. Section 907(a)(1)(A) is a direct response to efforts by the U.S. industry to produce and market flavored cigarettes in the United States. As we have demonstrated, the U.S. tobacco industry spent over a decade and untold amounts of money to develop, research and market “exotic” flavored cigarettes for the U.S. market and now can sell none of these products to their intended consumers.<sup>262</sup> Just as Indonesia claims an interest in selling and marketing its clove cigarettes in the United States, so U.S. producers claim an interest in marketing and selling the flavored brands in which they invested. Section 907(a)(1)(A) adversely affects both products.<sup>263</sup>

211. In addition, 907(a)(1)(A) is part of a broader statute which imposes a range of restrictions on all cigarettes sold in the United States, nearly all of which – 97% – are U.S.-produced. The FSPTCA establishes a broad range of measures which curtail the production of U.S. cigarette producers. By contrast, Indonesia’s cigarette exports to the United States comprised .07% of their cigarette exports in 2008.<sup>264</sup>

212. Article III:4 protects Members from discrimination based on origin – but does not protect foreign products from all adverse effects of a measure which, in pursuit of a legitimate objective, has an adverse impact upon a foreign product. The protections contained in the GATT 1994 are not designed, and should not be applied, to require that Members only can ban a specific class of cigarettes for a legitimate policy reason unless they ban all domestic cigarettes. Such an outcome would seriously hamper national regulatory prerogatives to minimize the harms of tobacco products.

### **C. Section 907(a)(1)(A) Is Not Inconsistent With TBT Article 2.1**

---

<sup>262</sup> See section III.G(6) and III.H.

<sup>263</sup> Indonesia asserts that sales of domestic tobacco and menthol cigarettes increased after Section 907(a)(1)(A) went into effect, apparently insinuating that the ban has benefitted U.S. producers. However, month-to-month comparisons are unreliable, given regular monthly fluctuations in cigarette manufacturer shipments and imports and related federal tax collections. Available data show that, comparing the ten month-period since Section 907(a)(1)(A) went into effect to the preceding 10-month period, the number of domestically produced cigarettes on which the federal cigarette tax was collected went down 7.1% and for imports went down 14.7%. This decline in federally taxed imports accords with past trends, as imports have declined in double-digits each year after 2004. The key point, however, is that the decline in domestically taxed cigarettes accelerated after Section 907(a)(1)(A) went into effect, demonstrating that the measure has not afforded protection to domestic production. Exhibit US-75 Indonesia has not and cannot support the notion that Section 907(a)(1)(A) is a “proxy” to exclude clove cigarettes from the U.S. market to the benefit of U.S. production.

<sup>264</sup> Exhibit US-75

213. As an initial matter, the United States notes that it is Indonesia’s burden to establish that Section 907(a)(1)(A) is a technical regulation.

214. The United States would not that certain textual and contextual differences should be taken into account in the Panel’s analysis of “likeness” and “less favourable treatment” under Article 2.1 of the TBT Agreement.

215. One such difference that the Panel should consider is the language in the Preamble of the TBT Agreement stating that “no country should be prevented from taking measures necessary [...] for the protection of human [...] life or health.” The TBT expressly contemplates that Article 2.1 should be applied consistently with Members’ ability to regulate in the interest of their citizens’ health.

216. It also should be noted that Article 2.1 states, in relevant part, that “Members shall require that *in respect of technical regulations*, products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin . . . .” (emphasis added). Thus, the obligation in Article 2.1 applies “in respect” of a technical regulation. Applying the customary rules of interpretation, the ordinary meaning of the term “respect” is “be directed to; refer to; relate to; deal with; be concerned with.” This textual difference should be considered in analyzing Article 2.1.

217. In particular, the panel should consider that a technical regulation, by definition, applies to products or groups of products that are similar enough – or similar in certain respects – so as to be an identifiable product or group of products.<sup>265</sup> Accordingly, a like product analysis under the TBT Agreement need be careful to distinguish between characteristics that make a product or group of products identifiable for purposes of the regulation, and characteristics that demonstrate a competitive relationship or substitutability in the marketplace.

#### **D. Conclusion on National Treatment Claims**

218. Indonesia has not met its burden under Article III:4 of the GATT 1994 or Article 2.1 of the TBT Agreement to show that Section 907(a)(1)(A) accords less favorable treatment to clove cigarettes than tobacco or menthol cigarettes based on the national origin of the products.

219. First, Indonesia has not demonstrated that clove cigarettes are like products to tobacco and menthol cigarettes. Under Article III:4 of the GATT 1994, a determination of likeness is premised on the substitutability of products in the market place and the existence of a competitive relationship. Indonesia has not demonstrated either. Additionally, the context of Article 2.1 of the TBT Agreement requires a carefully nuanced analysis of “likeness,” which Indonesia has not provided.

---

<sup>265</sup> *EC – Asbestos (AB)* para. 70.

220. Second, Indonesia has not demonstrated that Section 907(a)(1)(A) accords less favorable treatment to clove cigarettes than tobacco or menthol cigarettes based on their national origin. Section 907(a)(1)(A) applies identically to all cigarettes regardless of their origin. Moreover, Section 907(a)(1)(A) does not *de facto* discriminate based on national origin. Consistent with the United States GATT Article III:4 and TBT Article 2.1 obligations, Section 907(a)(1)(A) distinguishes among cigarettes based on their overall effects to the public health, and not based on their national origin. Section 907(a)(1)(A) adversely impacts upon both Indonesian and U.S.-produce cigarettes alike and does not afford protection to domestic industry.

**E. Section 907(a)(1)(A) Is Not Inconsistent with TBT Article 2.2**

221. Indonesia argues that Section 907(a)(1)(A) is more trade-restrictive than necessary to meet a legitimate objective and therefore is inconsistent with Article 2.2 of the TBT Agreement. Indonesia’s arguments should be rejected.

**1. Legal Overview of Article 2.2**

222. Article 2.2 of the TBT Agreement provides:

Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.

223. The first sentence of Article 2.2 establishes the general rule that Members shall ensure that technical regulations do not create unnecessary obstacles to international trade, while the second sentence of Article 2.2 explains that “for this purpose” “technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective.” In other words, the second sentence explains what the first sentence means. Article 2.2 also contains a non-exhaustive list of examples of “legitimate objectives” including protection of animal life or health or the environment and prevention of deceptive practices.

224. The preamble to the TBT Agreement recognizes:

that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health,

of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement.<sup>266</sup>

225. This preambular paragraph provides relevant context with respect to the words “legitimate objective” in Article 2.2. In particular, it makes clear that each Member has the right to decide for itself which legitimate objectives to pursue and to take measures to meet those objectives “at the levels it considers appropriate.” Similarly, TBT Article 2.7 speaks of ensuring that a technical regulation will “adequately fulfill the objectives,” thus also making clear that a Member is entitled to ensure that its legitimate objectives are “adequately fulfilled.”

226. As elaborated below, as a general matter, Section 907(a)(1)(A) is to fulfill the legitimate objective of protecting the public health. Specifically, the legitimate objective of Section 907(a)(1)(A) is to reduce youth smoking as appropriate for the protection of the public health, taking into account the negative consequences resulting from banning products that tens of millions of adults are chemically and psychologically dependent on. As noted in section III.H, 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. To not take the risk of such considerations, which are still being studied by FDA and others, into account could lead to the undermining, not improvement, of public health in the United States.

227. In light of the importance of public health, the United States has chose a high level of protection. Given the U.S. Government’s long and frustrating experience in trying to limit youth smoking, this high level of protection is evidenced by the measure applied – a ban. As explained below, Section 907(a)(1)(A) unquestionably fulfills this legitimate objective at the level the United States considers appropriate. Finally, Indonesia has failed to establish that any alternative measure fulfills the U.S. legitimate objective at the level it considers appropriate and is also significantly less trade-restrictive than Section 907(a)(1)(A). As such, Indonesia has failed to satisfy its burden to establish a breach of Article 2.2.

228. First, the United States will discuss the legitimate objective that Congress intended Section 907(a)(1)(A) to fulfill and why the measure fulfills the legitimate objective. Second, the United States will discuss the appropriate level that the United States requires and why Section 907(a)(1)(A) satisfies that level. Third, the United States will respond to Indonesia’s arguments as to what, in Indonesia’s view, the U.S. legitimate objective and appropriate level should be.

---

<sup>266</sup> TBT Agreement, 6<sup>th</sup> preambular paragraph.

Fourth, the United States will discuss how Indonesia has not provided an alternative measure that is reasonably available and fulfills the U.S. legitimate objective at the level it considers appropriate that is also significantly less trade restrictive than Section 907(a)(1)(A). Fifth, and finally, the United States will address various other invalid arguments of Indonesia.

## **2. Congress Included Section 907(a)(1)(A) in the FSPTCA in Order to Fulfill a Legitimate Objective**

229. Section 907(a)(1)(A) bans the sale of cigarettes (as well as component parts) that have a “characterizing flavor” except if that characterizing flavor is tobacco or menthol. As noted above, the measure is generally intended to fulfill the objective of protecting the public health. Specifically, the first part of the measure, the ban, is intended to fulfill the objective of reducing the rate of young people becoming smokers by eliminating certain products from the market place that have particular appeal to young people. The second part of the measure, the limited exception to the ban, is intended to ensure that a ban that reduces youth smoking be appropriate for the protection of the public health even when taking into account the risk of negative consequences for adult smokers, the U.S. health care system, and society more generally from eliminating products from the market that tens of millions of adults are addicted to.

### **(a) The Objective of Section 907(a)(1)(A) Is a Legitimate Objective for Purposes of Article 2.2**

230. The legitimate objective is the protection of human health, which is explicitly listed as a legitimate objective in Article 2.2. Further, Article 2.2’s list of legitimate objectives is non-exhaustive, as confirmed by the inclusion of the term “*inter alia*,” a point confirmed by the *EC – Sardines* panel that found two objectives not listed in Article 2.2 to be legitimate.<sup>267</sup> The measure seeks to protect the public health by reducing youth smoking as appropriate for the protection of the public health, taking into account the risk of negative consequences (including negatively impacting the health of addicted, adult smokers, protecting the integrity of the domestic health care system, and limiting the expansion of an unregulated, and illegal black market).

### **(b) Congress Intended Section 907(a)(1)(A) to Protect the Public Health by Reducing Youth Smoking as Appropriate While Taking Into Account the Risk of Negative Consequences**

231. As discussed above, smoking is “the foremost preventable cause of premature death in America,” causing “over 400,000 deaths in the United States each year,” as well as resulting in

---

<sup>267</sup> *EC – Sardines (Panel)*, para. 7.123 (concluding that market transparency and consumer protection are legitimate objectives).

approximately 8,600,000 Americans suffering chronic smoking related illnesses.<sup>268</sup> Congress properly views this issue as a “public health crisis,” and considered it in the “public interest” to enact comprehensive legislation “to protect the public health.”<sup>269</sup>

### **i. Reducing Youth Smoking**

232. Of the many concerns this public health crisis presents, one of the most troubling, and vexing, is the concern over youth smoking. As Congress has noted:

Almost 80% of new users of tobacco products began when they were under [18 years of age,] the minimum legal age to purchase them. The use of tobacco products by the nation’s children is a pediatric disease of considerable proportions that results in new generations of tobacco dependent children. Every day, approximately 3,500 youth try a cigarette for the first time, and another 1,000 will become new, regular daily smokers. One-third of these youth will eventually die prematurely as a result.<sup>270</sup>

233. Congress has also found that “[r]educing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today’s children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately \$75,000,000,000 in savings attributable to reduced health care costs.”<sup>271</sup>

234. Given the critical part youth smoking plays in the overall public health crisis in the United States, how difficult it has been to satisfactorily reduce youth smoking – at least in part because “cigarette companies continue to target and market to youth”<sup>272</sup> – Congress included Section 907(a)(1)(A) in the FSPTCA to specifically target those products that are being marketed because they have a particular appeal to youth. According to the HR Report:

Consistent with the overall intent of the bill to protect the public health, including

---

<sup>268</sup> FSPTCA, sec. 2, finding 13, Exhibit US-7.

<sup>269</sup> See FSPTCA, sec. 2, finding 29, Exhibit US-7; HR Rep’t, at 37, Exhibit US-67.

<sup>270</sup> HR Rep’t at 3. Exhibit US-67; see also FSPTCA, sec. 2, finding 1 (“The use of tobacco products by the Nation’s children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.”); FSPTCA, sec. 2, finding 4 (“Virtually all new users of tobacco products are under the minimum legal age to purchase such products.”). Exhibit US-7. For further discussion, please see section III.F.

<sup>271</sup> FSPTCA, sec. 2, finding 14. Exhibit US-7; see also section III.C.

<sup>272</sup> FSPTCA, sec. 2, finding 47 (citing U.S. district court’s opinion in *United States v. Philip Morris*, Civil Action No. 99-2496 (GK) (August 17, 2006)), Exhibit US-7.



by reducing the number of children and adolescents who smoke cigarettes, section 907(a)(1) is intended to prohibit the manufacture and sale of cigarettes with certain “characterizing flavors” *that appeal to youth*. Examples of these products include, but are not limited to, those introduced in recent years such as “Mandalay Lime,” “Warm Winter Toffee,” “Mocha Taboo,” and “Midnight Berry,” which were the subject of an investigation and subsequent settlement agreement between one cigarette manufacturer and the attorneys general of 40 states in October 2006. Accordingly, this section prohibits the use of any constituent or additive that causes a cigarette or its smoke to have a characterizing flavor other than menthol or tobacco.<sup>273</sup>

235. Given this evidence in both the text of the FSPTCA as well as in its legislative history, it is clear that Congress intended the banning of flavored cigarettes to reduce youth smoking.<sup>274</sup>

**ii. Reducing Youth Smoking as Appropriate for the  
Protection of the Public Health, Taking Into Account  
the Risk of Negative Consequences**

236. Congress was equally clear as to why it made an exception for cigarettes that have a characterizing flavor of tobacco or menthol: banning such products would eliminate products that tens of millions of adult Americans have been consuming, legally, for their entire lifetimes, and on which they are chemically and psychologically dependent on. Congress quite rightly needed to consider that the negative consequences that could occur from stripping these products from tens of millions of people could be counter-productive from a public health standpoint, notwithstanding the fact that many youths smoke tobacco and menthol-flavored cigarettes. Congress noted, however, the case is very different from the products covered by Section 907(a)(1)(A):

The Committee has reviewed the products that will be banned after 90 days under this section and has concluded that the ban will not lead to negative public health effects, because of how the affected products generally are used and because of their low overall use by adult smokers. Specifically, none of the cigarettes covered by the ban – including those with the characterizing flavors of fruit, chocolate, *and clove* – is used regularly by a large number of addicted adult smokers. Instead, these cigarettes tend to be used only occasionally, either by regular users of other products, by individuals who are experimenting with tobacco use, or by those who smoke only in certain social settings. Given that few adult smokers ever use the flavored cigarettes that will be banned and that most

---

<sup>273</sup> HR Rep’t, at 37 (emphasis added). Exhibit US-67.

<sup>274</sup> The United States notes that Indonesia agrees that reducing youth smoking is a legitimate objective for purposes of Article 2.2. See Indonesia First Written Submission, para. 80.

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.

All of these 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.<sup>275</sup>

237. As noted in section III.H, there is ample evidence to support Congress’s conclusions in this regard.

238. Accordingly, the evidence establishes that Section 907(a)(1)(A) is intended to serve the legitimate objective of protecting the public health by reducing youth smoking without causing the potential negative consequences discussed above. This thus reflects the balance that Congress needed to strike in further restricting smoking, which accounts for 1 in 5 deaths annually,<sup>276</sup> but which is a legal product, consumed by approximately 20% of the adult U.S. population, or 46 million people.<sup>277</sup>

**(c) Section 907(a)(1)(A) Fulfills Its Legitimate Objective**

239. Section 907(a)(1)(A) fulfills the legitimate objective that Congress intended it to fulfill.

**i. Section 907(a)(1)(A) Only Bans Cigarettes That Can Be Properly Considered “Starter” or “Trainer” Products Not Regularly Used by the U.S. Adult Population**

240. Section 907(a)(1)(A) fulfills the legitimate objective of protecting the public health by reducing youth smoking while avoiding the negative consequences that could result from

---

<sup>275</sup> HR Rep’t, at 38 (emphasis added), Exhibit US-67.

<sup>276</sup> HR Rep’t at 2, Exhibit US-67.

<sup>277</sup> See section III.A.

prohibiting products that tens of millions of adults are addicted to by only prohibiting those products that serve as “starter” or “trainer” cigarettes for young smokers, and which are not regularly used by adult smokers.<sup>278</sup> This is seen by the evidence that flavored cigarettes – except for menthol – are disproportionately smoked by novice young smokers (both minors and young adults), rather than already addicted, older adult smokers.<sup>279</sup>

241. As noted above, Congress specifically considered this issue in deciding what products to ban, and what to exempt, looking carefully at what products could properly be considered “trainer” or “starter” products, rather than the brands/products “regular[ly] use[d] . . . by heavily addicted adult smokers.”<sup>280</sup>

242. In contrast, increasing the scope of the ban to include either one or both of the non-covered flavorings – tobacco and menthol – would not fulfill Congress’s legitimate objective as it would prohibit the sale of cigarettes whose consumption by addicted adults is far from “negligible,”<sup>281</sup> accounting for the vast majority of cigarettes sold and consumed in the United States.

243. This is not to say that Congress does not want to decrease the number of addicted, adult smokers directly, rather than indirectly by reducing the rate of new young smokers entering the market place as older smokers die at a constant rate. The FSPTCA directly addresses the problem posed by the addicted, adult smoking population by disclosing product information, prohibiting misleading advertising and marketing, etc. And, in fact, the Congressional Budget Office estimates that overall consumption of tobacco products in the United States will further decline as a result of the enactment of the FSPTCA.<sup>282</sup>

## **ii. Indonesia’s Arguments to the Contrary Are Unsupportable**

244. Indonesia agrees with the United States that the rates that clove cigarettes are consumed by young people versus adults is a key fact to determine in this case, and appears to concede that

---

<sup>278</sup> See section III.E(2).

<sup>279</sup> See section III.F.

<sup>280</sup> See HR Rep’t, at 38, Exhibit US-67.

<sup>281</sup> HR Rep’t at 38, Exhibit US-67.

<sup>282</sup> HR Rep’t at 19-20, Exhibit US-67.

at least certain flavored cigarettes, such as “candy” flavored ones, are [“trainer”] products.<sup>283</sup> Nevertheless, Indonesia draws a distinction between such products and clove cigarettes, arguing that the latter are not attractive to youth.<sup>284</sup> As discussed above, the academic literature and surveys of the last decade support the proposition that youths are disproportionately attracted to cigarettes flavored with cloves, chocolate, liquor, and the like.<sup>285</sup> This is in stark contrast to menthol cigarettes, which are consumed by young and adult smokers alike.

245. As an initial matter, Indonesia argues that clove cigarettes do not in fact attract youth smoking.<sup>286</sup>

246. First, Indonesia contends that “zero” youth smokers smoke clove cigarettes, a point that is contradicted in the immediately subsequent paragraph of Indonesia’s first written submission.<sup>287</sup> As discussed in section III.F, Indonesia’s support for this point, the 2007 and 2008 NSDUH surveys, is not as reliable a measure of clove consumption by young Americans as earlier NSDUH surveys.

247. Second, Indonesia attempts to minimize the Klein Study, which Indonesia claims is “the most frequently cited justification for a ban,” but yet does not mention clove cigarettes.<sup>288</sup> The fact that clove cigarettes are not mentioned in this study is irrelevant – the point is that young people are attracted to flavored cigarettes, and clove is indisputably just such a flavor. Moreover, the Klein survey is but one of many surveys on youth smoking in the United States, as discussed in section III.F.

248. Third, Indonesia attempts to argue, based on a single source, Dr. Michael Siegel, that in

---

<sup>283</sup> Indonesia First Written Submission, para 89 (“In large measure, the answer to this question depends on whether clove cigarettes are more like those cigarettes smoked by adults, which are excluded from the ban, or whether they are more like the ‘candy’ flavours designed and marketed to attract kids to smoke.”).

<sup>284</sup> See Indonesia First Written Submission, paras. 92-96.

<sup>285</sup> See section III.E(3).

<sup>286</sup> See Indonesia First Written Submission, paras. 92-96. Indonesia’s argument that most youths smoke tobacco or menthol-flavored products rather than clove-flavored cigarettes is uncontested, but irrelevant. See Indonesia First Written Submission, paras. 92-93. A measure banning these products would not fulfill the United States’ legitimate objective.

<sup>287</sup> Compare Indonesia First Written Submission, para. 94 (“In 2007, only .1% of youth smokers used clove cigarettes and by 2008 that number had fallen to zero.”), with *id.* at para. 95 (acknowledging that 12<sup>th</sup> graders (who typically range between 17 and 18 years of age) consume clove cigarettes).

<sup>288</sup> Indonesia First Written Submission, paras. 99-101.

fact flavored cigarettes *generally* are not “gateway” products.<sup>289</sup> Dr. Siegel’s writings are posted to his own blog, not a peer review journal, and should be treated with caution. This is especially true given that Dr. Siegel’s conclusions run counter to not only the extensive science on this issue, but to consumer preferences of American youth, and the intention of the tobacco industry.<sup>290</sup> Moreover, the United States notes that Indonesia undercuts the persuasiveness of its own source as it appears to disagree with Dr. Siegel, taking the position that “candy” flavored cigarettes have in fact been “designed and marketed to attract kids to smoke.”<sup>291</sup>

249. Finally, Indonesia strongly implies that clove cigarettes are only smoked by adults, based on either questionable sources, or on Indonesia’s own misuse of the data, to make this demonstrably false conclusion.<sup>292</sup> The evidence shows that clove cigarettes, like cigarettes flavored with chocolate, vanilla, and the like, are overwhelmingly favored by teenagers and young adults people rather than adults.<sup>293</sup>

### **3. Section 907(a)(1)(A) Fulfills the Legitimate Objective at the Level That the United States Finds Appropriate**

250. As noted above, a Member is entitled to ensure that its measures satisfy the Member’s level of protection, which the Member may set at whatever level it deems appropriate.

251. Although smoking rates of young people, as well as the population at large, had been in decline for a number of years, Congress has found that the number of smokers, particularly

---

<sup>289</sup> See Indonesia First Written Submission, para. 102 (relying on Dr. Michael Stiegel’s writings) (Exhibit IND-37).

<sup>290</sup> See section III.F.

<sup>291</sup> Indonesia First Written Submission, para. 89 (“In large measure, the answer to this question depends on whether clove cigarettes are more like those cigarettes smoked by adults, which are excluded from the ban, or whether they are more like the ‘candy’ flavours designed and marketed to attract kids to smoke.”).

<sup>292</sup> See Indonesia First Written Submission, para. 94 (“In 2007, only .1% of youth smokers used clove cigarettes and by 2008 that number had fallen to zero.”) (emphasis in original).

<sup>293</sup> See section III.F. Indonesia further cites an apparently commissioned survey of whether American teens had ever heard of “kretek.” See Indonesia First Written Submission, para. 96. Such an inquiry is entirely irrelevant as the Indonesian product is referred to in the United States as “cloves” or “clove-flavored cigarettes.” The term “kretek” is not normally used in American parlance and there is no reason to believe that any American, even one that smokes clove cigarettes, would have ever heard of the term “kretek.” In fact, the Opinion Research Corporation study appears to prove too much as – taken literally, no teen has ever smoked a clove cigarette or even heard of someone else smoking one – contradicting a study Indonesia relies on in the immediately preceding paragraph that acknowledges that 12<sup>th</sup> graders (who typically range between 17 and 18 years of age) consume clove cigarettes. See Indonesia First Written Submission, para. 95.

young smokers, remains “unacceptably high.”<sup>294</sup> Moreover, as noted in the H.R. Report, Congress concluded that smoking was not in decline in all demographics, particularly with regard to the critical demographic of high school students (young people aged 14-18), where the incidence of smoking was actually increasing (21.9% in 2003 to 23% in 2005).<sup>295</sup> Such a situation was “particularly alarming” to Congress given that not only had the MSA restrictions on youth targeted advertising been in place since 1998, but also in light of the apparent lack of success of “the state excise tax increases, prevention and cessation programs, and smokefree air laws, which cumulatively should have forced youth smoking rates down below the current level.” As Congress noted, “[m]ajor scientific reports issued after the MSA . . . all found a continuing serious problem despite prior efforts and concluded that *additional restrictions* on tobacco marketing are essential to reduce tobacco use, especially among youth.”<sup>296</sup>

252. Congress further concluded that a significant problem in the continued challenge of youth smoking was “[t]he current lack of government regulation [that] has allowed the tobacco industry to design new products or modify existing ones in ways that increase their appeal to children and that contribute to the risk and incidence of disease. Flavors and product modification not only make the products more appealing to youth, but often result in exposure to additional carcinogens and other toxic constituents.”<sup>297</sup> Consistent with this conclusion, 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*.”<sup>298</sup>

253. Section 907(a)(1)(A) represents such a comprehensive restriction on the sale of these products that appeal to youths but have negligible regular use by adult smokers, and was a necessary step in order to further reduce youth smoking given that previous efforts of advertising restrictions and the like had, in Congress’s own words, “failed.”<sup>299</sup>

---

<sup>294</sup> HR Rep’t, at 33, Exhibit US-67.

<sup>295</sup> HR Rep’t at 33, Exhibit US-67.

<sup>296</sup> HR Rep’t at 33, (emphasis added). Exhibit US-67.

<sup>297</sup> HR Rep’t at 4, Exhibit US-67.

<sup>298</sup> FSPTCA, sec. 2, finding 6 (emphasis added). 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.”

<sup>299</sup> FSPTCA, sec. 2, finding 6, Exhibit US-7; *see also* HR Rep’t at 3 (“Past efforts to restrict the advertising and marketing of tobacco products to youth have failed to adequately curb tobacco use by adolescents. H.R. 1256 provides FDA with the authority it needs to promulgate comprehensive restrictions on the sale, promotion, and distribution of tobacco products, actions that most public health experts agree can significantly reduce the number of people who start to use tobacco and significantly increase the number of people who quit using tobacco.”). Exhibit

254. Accordingly, the seriousness of the problem of youth smoking is evidenced by the type of measure Congress employed – a ban. Section 907(a)(1)(A)’s prohibition of flavored cigarettes that are only used as “trainer” products while exempting those products that are not uniquely attractive to youth, fulfills the legitimate objective of protecting the public health at the level the United States considers appropriate. Specifically, Congress believed it was necessary to increase the protection of youths above what current requirements on advertising, labeling, etc. provided for while taking into account the risk of negative consequences that, if they happened, could undermine the protection of the public health that Congress seeks to fulfill.

#### **4. Indonesia’s View of What the U.S. Legitimate Objective and Appropriate Level Are Is Not Supportable**

255. As discussed above, each Member has the right to decide for itself which legitimate objectives to pursue and which levels it considers appropriate. In its First Written Submission, Indonesia offers its view as to what the U.S. legitimate objective and level of protection are. In doing so, Indonesia commits numerous errors.

256. Indonesia argues that by banning clove cigarettes while allowing cigarettes that youths mainly consume (tobacco and menthol flavored), the U.S. measure “greatly exceeds” the alleged level of protection and that less trade restrictive measures would fulfil Indonesia’s view of what the U.S. legitimate objective is, namely, reducing youth smoking.<sup>300</sup>

257. In determining the United States’ alleged legitimate objective/appropriate level of protection, Indonesia fails to properly understand Congress’s findings, the House Report, the entirety of the legislative history of the FSPTCA, and the text of Section 907(a)(1)(A) as discussed above. As such, Indonesia’s alleged legitimate objective/appropriate level of protection ignores the balance that Congress is striking in the FSPTCA generally and Section 907(a)(1)(A) specifically, and is unquestionably incorrect.

#### **5. Indonesia Has Failed to Establish That an Alternative Measure Fulfills the U.S. Legitimate Objective at the Level That the United States Considers Appropriate That Is Also Significantly Less Trade-Restrictive**

258. Article 2.2 of the TBT Agreement provides that technical regulations shall not be “more trade-restrictive than necessary” to fulfill a legitimate objective. As discussed below, a measure that fulfills its legitimate objective at the level the Member finds appropriate is not, as a matter of law, more trade-restrictive than necessary unless the complaining Member proves that an

alternative measure exists that is reasonably available, also fulfills the respondent Member's legitimate objective at the level the importing Member finds appropriate and is significantly less trade restrictive than the challenged measure. Indonesia has not put forth any evidence that even one of the numerous measures it has culled from various sources satisfies this standard, and, therefore, has not satisfied its burden of establishing a *prima facie* case of inconsistency.

**(a) The Proper Interpretation of the Meaning of What Is More Trade Restrictive Than Necessary to Fulfill the Legitimate Objective Must Flow From the Text of Article 2.2**

259. The TBT Agreement does not define the phrase “more trade-restrictive than necessary” and it has not been extensively reviewed by previous panels or the Appellate Body. Based on the text of Article 2.2, Indonesia would need to establish two elements for the measure to be considered more trade-restrictive than necessary: (1) the measure must be trade-restrictive; and (2) the measure must restrict trade more than is necessary to fulfill the Member's legitimate objective.

260. With respect to the first element (and applying the customary rules of treaty interpretation reflected in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties* (“VCLT”)), the ordinary meaning of the word “restrictive” is “having the nature or effect of a restriction; imposing a restriction.”<sup>301</sup> “Restriction” is defined as “a thing that restricts someone or something ... the act of restricting someone or something.”<sup>302</sup> “Restrict” is defined as “to limit, bound, confine ... restrain by prohibition, prevent.”<sup>303</sup> A measure that is trade-restrictive, therefore, could include one that restricts trade, i.e., that limits, prevents or confines trade, or restrains it by prohibition.

261. With respect to the second element, the ordinary meaning of the word “necessary” is “that cannot be dispensed with or done without; requisite, essential, needful ... requiring to be done; that must be done.”<sup>304</sup> A measure that is “more” trade-restrictive than “necessary” is therefore a measure that restricts trade more than is needed or required to fulfill the Member's legitimate objective. The word “more” implies a comparison. In other words, there is another measure that can fulfill the legitimate objective that would restrict trade less. This comparison in turn implies that other reasonably available measures that fulfill the measure's legitimate objective should be examined to determine whether the measure at issue is “more” trade restrictive than what is required or necessary to fulfill that Member's objective.

---

<sup>301</sup> *New Shorter Oxford English Dictionary*, vol. 2, at 2569 (1993). Exhibit US-77.

<sup>302</sup> *New Shorter Oxford English Dictionary*, vol. 2, at 2569 (1993). Exhibit US-77.

<sup>303</sup> *New Shorter Oxford English Dictionary*, vol. 2, at 2569 (1993). Exhibit US-77.

<sup>304</sup> *New Shorter Oxford English Dictionary*, vol. 2, at 1895 (1993). Exhibit US-78.



262. In addition to the ordinary meaning of a term, the customary rules of interpretation also involve looking at the context. Article 5.6 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”), which includes a provision similar to Article 2.2 of the TBT Agreement, provides relevant context for the interpretation of Article 2.2 of the TBT Agreement within the meaning of Article 31.2 of the VCLT.

263. That SPS provision provides in relevant part that “when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.”<sup>305</sup> A footnote to Article 5.6 clarifies that “a measure is not more trade restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.”<sup>306</sup> This relevant context confirms that determining whether a measure is “more trade-restrictive than necessary” within the meaning of Article 2.2 of the TBT Agreement involves determining whether there is a reasonably available alternative measure that could fulfill the Member’s objective that is significantly less trade-restrictive.

264. In *Australia – Salmon*, the Appellate Body confirmed that, in order to find a violation of SPS Article 5.6, three elements must be established: “there is an SPS measure which: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the Member’s appropriate level of sanitary or phytosanitary protection; and (3) is significantly less restrictive to trade than the SPS measure contested.” The Appellate Body observed that the three prongs are cumulative in nature, in that in order to establish inconsistency all of them have to be satisfied.<sup>307</sup> And if any of those elements are not fulfilled, the measure in dispute would be

---

<sup>305</sup> SPS Agreement, Article 5.6.

<sup>306</sup> SPS Agreement, Article 5.6, footnote 3. This interpretation is confirmed by a December 15, 1993 letter from the Director-General of the GATT to the Chief U.S. Negotiator concerning the application of Article 2.2 of the TBT Agreement. That letter explains that while “it was not possible to achieve the necessary level of support for a U.S. proposal [concerning a clarifying footnote to Article 2.2 and 2.3 of the TBT Agreement] . . . it was clear from our consultations at expert level that participants felt it was obvious from other provisions of the [TBT] Agreement that the Agreement does not concern itself with insignificant trade effects nor could a measure be considered more trade restrictive than necessary in the absence of a reasonably available alternative.” Letter from Peter D. Sutherland, Director-General of the GATT, to Ambassador John Schmidt, Chief U.S. Negotiator (December 15, 1993), Exhibit US-79. This letter provides supplemental means of interpretation within the meaning of Article 32 of the Vienna Convention, in particular as circumstances of the TBT Agreement’s conclusion, that confirms the meaning derived from the ordinary meaning, in context, and in light of the object and purpose of the TBT Agreement. VCLT, Article 32.

<sup>307</sup> *Australia – Salmon (AB)*, para. 194.

consistent with Article 5.6.<sup>308</sup>

265. The same test applies equally in the TBT Article 2.2 context. Indonesia has not satisfied this test.

**(b) The Meaning of the Term “Necessary” as Used in the 1994 GATT Article XX Context Is Not Instructive to Understanding the Meaning of TBT Article 2.2**

266. Indonesia argues that the Panel should import the meaning of the term “necessary,” as used in Article XX of the GATT 1994 and as understood by the Appellate Body and previous panels, to control the TBT Article 2.2 “more trade restrictive than necessary” test.<sup>309</sup> Such an approach is without basis and is unwarranted.<sup>310</sup> The proper interpretation of this test flows from the text of Article 2.2 itself and any relevant context in accordance with Articles 31 and 32 of the VCLT. The term “necessary” in Article XX is being used in a different sense to cover a different set of circumstances. Accordingly, 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.

**i. GATT 1994 Article XX Does Not Inform as to the Meaning of TBT Article 2.2**

267. Given the significant differences between Article XX of the GATT 1994 and TBT Article 2.2, it would not be appropriate to rely on GATT 194 Article XX interpretations in the analysis of TBT Article 2.2. In particular, the term “necessary” is used in GATT 1994 Article XX in a different context than in TBT Article 2.2. Under TBT Article 2.2, a panel is inquiring as to whether a measure fulfills a legitimate objective is “more trade restrictive than necessary” to fulfill that objective. On the other hand, under GATT Article XX, the question is whether it is “necessary” to breach the GATT 1994 to protect human, animal or plant life or health, to protect public morals or to secure compliance with laws or regulations. Thus, the alternatives that are being compared under TBT Article 2.2 are two alternatives that are WTO-consistent while the alternatives being compared under GATT Article XX are an alternative that is WTO-inconsistent and another that is WTO-consistent. And, unlike under Article XX, it is the complaining party

---

<sup>308</sup> *Australia – Salmon (AB)*, para. 194.

<sup>309</sup> *See, e.g.*, Indonesia First Written Submission, paras. 75-78.

<sup>310</sup> Indonesia’s sole basis for taking this radical approach is its view that the United States argued such a view in a third party submission before the Appellate Body in *EC – Asbestos*. *See* Indonesia First Written Submission, para. 76. Indonesia is in error. First, even assuming that prior third party views of the United States are as dispositive as Indonesia implies, the United States made no such argument in *EC – Asbestos*, instead making the non-surprising argument that the facts relevant to GATT Article XX analysis would be relevant to TBT Article 2.2 analysis. *See* U.S. Third Party Submission in *EC – Asbestos*, para. 33. Exhibit US-80.

that has the burden of establishing that the measure is “more trade-restrictive than necessary” under Article 2.2.

268. Further, there is no textual basis to apply the panel and Appellate Body’s interpretive approach to GATT Article XX to Article 2.2 of the TBT Agreement. Under the VCLT, 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 ordinary meaning of “more trade restrictive than necessary” is outlined above and, as noted, relevant context for Article 2.2 of the TBT Agreement is Article 5.6 of the SPS Agreement. The VCLT also provides that recourse may also be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion. As noted above, a letter from the Director-General of the GATT to the Chief U.S. Negotiator confirms that Article 2.2 of the TBT Agreement should be interpreted similarly to Article 5.6 of the TBT Agreement. 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.

**ii. Indonesia’s Analytical Approach Is Not Relevant to the Issue to Be Decided**

269. The result of Indonesia incorrectly framing the TBT Article 2.2 standard in GATT 1994 Article XX terms is that it leads Indonesia to ask (and answer) the wrong questions. The United States will not refute every statement Indonesia makes in this section as many of them are entirely irrelevant to the proper interpretation of the “more trade-restrictive than necessary” test. For example, Indonesia argues:

- the “question is whether it is necessary to ban clove cigarettes in order to reduce youth smoking”;<sup>311</sup>
- in undertaking its analysis of the “more trade-restrictive than necessary” test, “the Panel should evaluate the likely impact of not banning clove cigarettes”;<sup>312</sup>
- “if it is not necessary to ban the tobacco products that are most widely used by adolescents, it cannot be necessary to ban clove cigarettes, which are rarely used”;<sup>313</sup> and

---

<sup>311</sup> Indonesia First Written Submission, para. 86 (relying on the Article XX discussion in *US – Gasoline (Panel)*).

<sup>312</sup> Indonesia First Written Submission, para. 89.

<sup>313</sup> Indonesia First Written Submission, para. 98.

- the ban on clove cigarettes must at least make “a contribution to,” if not be “indispensable” to, the legitimate objective for the measure to satisfy the trade-restrictiveness test.<sup>314</sup>

None of these statements are relevant to the question of whether Section 907(a)(1)(A) is more trade restrictive than necessary. That issue can only be answered by determining whether Indonesia has adduced sufficient evidence to prove that an alternative measure exists that is reasonably available, fulfills the U.S. legitimate objective at the level that the United States considers appropriate and is significantly less trade restrictive than Section 907(a)(1)(A) is. As discussed below, the answer to this question is unquestionably no.

**(c) Indonesia Has Failed to Adduce Any Evidence That Proves Section 907(a)(1)(A) Is More Trade-Restrictive Than Necessary**

270. In paragraphs 106-111, Indonesia simply lists a number of different restrictions drawn from other parts of the FSPTCA, the 2006 RJ Reynolds Consent Agreement, the laws of Singapore and Australia, and the *Framework Convention on Tobacco Control*. Indonesia briefly references these restrictions without providing any evidence that any of these restrictions fulfill the U.S. legitimate objective at the level of protection it finds appropriate or that they are significantly less trade restrictive than Section 907(a)(1)(A) is.

271. A complaining party does not discharge its burden of establishing a *prima facie* case by simply making reference to alternative measures – it must adduce by way of sufficient evidence a for each relevant part of the legal standard presumption of inconsistency.<sup>315</sup> In other words, it is incumbent on Indonesia, in the first instance, to produce evidence that establishes that an alternative measure: (1) is reasonably available; (2) fulfills the challenged measure’s legitimate objective; (3) at the level the United States finds appropriate; and (4) that the measure is significantly less trade restrictive than Section 907(a)(1)(A). This evidence must prove these elements given the overall context of smoking restrictions in the United States, including all the anti-smoking restrictions applicable in the United States, whether existing prior to the FSPTCA, contained in the FSPTCA, or done pursuant to the FSPTCA.<sup>316</sup> Innuendos and implications are

---

<sup>314</sup> Indonesia First Written Submission, para. 103 (citing the Article XX discussion in *Korea – Beef (AB)*).

<sup>315</sup> See, e.g., *US – Gambling (AB)*, para. 140, stating that a “prima facie case must be based on ‘evidence and legal argument’ put forward by the complaining party in relation to each of the elements of the claim.” A complaining party must go beyond simply identifying an offending law. It must provide sufficient analysis of the law’s “basic import [and] identify the relevant WTO provision and obligation contained therein, and explain the basis for the claimed inconsistency of the measure with that provision.” *US – Gambling (AB)*, para. 141 (quoting *US – Wool Shirts and Blouses (AB)*).

<sup>316</sup> In this regard, the United States notes that several of the measures Indonesia references are already applicable on companies selling cigarettes in the United States now. See, e.g., Indonesia First Written Submission, paras. 110 (referring to requirements that cigarette vending machines are not accessible to minors; and prohibiting

not enough – Indonesia must satisfy its burden and establish a *prima facie* case of inconsistency. Until then, there is nothing for the United States to respond to.

## 6. Indonesia’s Various Other Arguments Are Similarly in Error

272. Finally, Indonesia makes a number of other arguments that do not appear to be relevant to the “more trade restrictive than necessary” analysis.

273. First, Indonesia argues that as “a ban is the most trade restrictive measure that can be adopted” it must therefore “be subject to the highest level of justification.”<sup>317</sup> There is no support in the text of the TBT Agreement or the DSU for such a position. The test is the same for all challenged measures under Article 2.2 – whether an alternative measure exists that fulfills the Member’s legitimate objective at the level of protection the Member considers appropriate and is significantly less trade restrictive than the challenged measure. A panel must judge whether this is the case based on an “objective assessment of the facts” consistent with the DSU’s Article 11. Neither the legal standard of TBT Article 2.2, nor the standard of review as set out in DSU Article 11 vary with the nature of the challenged measure.

274. Second, Indonesia argues that clove cigarettes are no more dangerous than other types of cigarettes.<sup>318</sup> This argument both lacks any connection to the requirements of Article 2.2, and misses the point of Section 907(a)(1)(A). Cigarettes flavored with cloves, chocolate, and other flavors are not banned because they are more dangerous on a per-use basis than tobacco or menthol-flavored cigarettes. Rather, these flavored cigarettes are banned because they have no countervailing public health impact associated with established population of addicted, adult smokers consuming them as their primary cigarette product.

275. Third, Indonesia misconstrues the meaning of Article 2.2 by implying that whether the measure is an unnecessary obstacle to trade is an independent prong of the analysis to be interpreted separately from the rest of Article 2.2.<sup>319</sup> As the United States explained above, the first sentence of Article 2.2 (where the phrase “unnecessary obstacles to international trade” appears) is explained in the second sentence. Therefore, if the Member’s measure is consistent with the second sentence of Article 2.2 it, by law, is not an “unnecessary obstacle[] to

---

the sale of cigarettes individually or in small packets).

<sup>317</sup> Indonesia First Written Submission, para. 80.

<sup>318</sup> See Indonesia First Written Submission, paras. 90-91.

<sup>319</sup> See Indonesia First Written Submission, section V(B)(2)(a) at para. 112.

international trade” and is consistent with Article 2.2 writ large.<sup>320</sup>

276. For the reasons explained above, the United States has acted consistently with the obligations of TBT Article 2.2.

**F. Indonesia Has Not Shown That the United States Acted Inconsistently With Its Obligations Under TBT Article 2.5**

277. Indonesia contends that the United States has acted inconsistently with TBT Article 2.5 by not providing “a complete response” to Indonesia’s questions regarding Section 907(a)(1)(A) that provides “scientific evidence” and “refers to the terms of TBT Articles 2.2, 2.3, and 2.4.”<sup>321</sup> Indonesia misunderstands the obligation.

278. TBT Article 2.5, first sentence provides, in relevant part:

A Member preparing, adopting, or applying a technical regulation which may have a significant effect on the trade of other Members, shall upon the request of another Member, explain the justification for that technical regulation in terms of paragraphs 2 to 4.

279. According to the text, this provision requires a Member to explain its justification for a technical regulation when another Member inquires about the measure. Article 2.5 requires the Member to whom the request is made to provide a justification for its measure in the terms provided in the relevant provisions of the TBT Agreement. Contrary to Indonesia’s assertion in paragraphs 128-133 of its First Written Submission, TBT Article 2.5 does not require the responding Member to answer every specific detailed question that it receives, including questions that do not relate to Articles 2.2, 2.3, or 2.4.

---

<sup>320</sup> Further, Indonesia’s factual basis for the argument – that the “burden of the ban fell almost exclusively on imported products [as] virtually no domestically produced cigarettes were banned.” is similarly not relevant to the analysis. *See* Indonesia First Written Submission, section V(B)(2)(a) at para. 112. First, the question of whether the burden falls more heavily on foreign or domestic goods is not relevant to an Article 2.2 claim and Indonesia provides no reason why it should be. Second, as the discussed above in sections III.E(3) and III.H, Congress’s concern was by far dominated by the products being rolled out by U.S. companies. *See* HR Rep’t, at 37, Exhibit US-67(making explicit reference to the RJ Reynolds’ brands “Mandalay Lime” and “Warm Winter Toffee” and the Brown & Williamson brands “Midnight Berry” and “Mocha Taboo”); *see also* section III.E(3) (explaining all the flavored brands that the U.S. companies produced prior to the enactment of the FSPTCA). The fact that RJ Reynolds had agreed to withdraw many of these products from the market prior to the legislation, did not obviate the need for the legislation. As discussed in section III.G(4), the 2006 settlement between RJ Reynolds and certain state attorney generals only applied to that one company and to the states involved. The prospect of other U.S. companies or foreign companies producing flavored “gateway” cigarettes for the U.S. market remained, and, at least with regard to clove cigarettes, the threat was ongoing, not merely prospective.

<sup>321</sup> Indonesia First Written Submission, paras. 130-132.

280. In the instant dispute, the United States acted consistently with Article 2.5 and has explained the objectives of its measure and provided its justification for the measure’s enactment. In fact, the United States and Indonesia have had numerous exchanges on this issue. For example, the United States agreed to make special arrangements to have a bilateral discussion with Indonesia in Geneva on August 27, 2009. The very next week, the U.S. Trade Representative, Ambassador Ronald Kirk, to discuss Indonesia’s concerns while at a WTO Ministerial in India. This exchange was then itself followed by a discussion of the issue at the November 2009 TBT Committee meeting by the delegations of the respective countries.

281. At each of these opportunities, the United States explained to Indonesia that the United States has applied the measure for the protection of public health, in particular the health of young Americans. For example, according to the minutes of the November 2009 TBT Committee meeting:

The representative of the United States indicated that the United States was not going to reverse the ban on clove cigarettes given the high priority the Obama Administration placed on protecting the health of Americans, especially youth. US health authorities support a ban on clove cigarettes to protect the public health. He noted that clove cigarettes were particularly appealing to youth and represented a “starter product” that could lead to the use of regular cigarettes. In particular, he stressed that clove cigarettes made it easier for new smokers to start smoking by masking the harshness of cigarette smoke and, like other banned fruit flavours, could ease the transition to addiction. Evidence also indicated that clove cigarettes could pose a range of additional health risks over conventional cigarettes. With regard to the allegation of discrimination, the US representative noted that substantial differences related to consumption, use patterns, and epidemiology existed between clove and menthol cigarettes, which made the two situations not comparable. He noted that the US Food and Drug Administration (FDA) had established a Scientific Advisory Committee that would support additional studies of menthol cigarettes before deciding an appropriate public health action. His delegation was open to further discussing the issue with Indonesia, so that Indonesian regulators could better understand the scientific basis for the US action.<sup>322</sup>

282. Moreover, and as discussed extensively above, the FSPTCA provides a full justification of itself in the initial sections of the law, which is further supplemented in the legislative history of the FSPTCA.<sup>323</sup>

---

<sup>322</sup> TBT Committee, *Minutes of the Meeting 5-6 November 2009*, G/TBT/M/49, at para. 7 (December 2009).

<sup>323</sup> See section III.H.

283. Accordingly, the United States has thus fully explained the “justification” for Section 907(a)(1)(A).

284. In light of these facts, Indonesia’s Article 2.5 claim amounts to nothing more than an expression of Indonesia’s dissatisfaction with the explanation provided by the United States. As is clear from the text of Article 2.5, however, all that is required of the importing Member is that it must explain the justification for its measure. Article 2.5 does not require that a Member maintaining a technical regulation must answer any and every question to the satisfaction of the requesting Member.

285. For the reasons explained above, Indonesia has failed to show that the United States acted inconsistently with the obligation of Article 2.5, first sentence.

**G. Indonesia Has Not Shown That Section 907(a)(1)(A) Is Inconsistent With Article 2.8**

286. Indonesia contends that TBT Article 2.8 provides that “a Member’s technical regulations must require products to meet a certain performance level rather than merely specify how products must be made or what they must contain.”<sup>324</sup> Indonesia concludes that “by basing the ban on clove cigarettes in the Special Rule on descriptive characteristics, the United States has violated Article 2.8 of the TBT Agreement.”<sup>325</sup> Indonesia’s argument is in error.

287. TBT Article 2.8 provides:

*Wherever appropriate*, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics. (Emphasis added)

288. As noted above, the Section 907(a)(1)(A) is structured in terms of descriptive characteristics, providing that cigarettes may not contain additives, flavors, herbs, or spices that give the cigarette a “characterizing flavor” other than tobacco or menthol.

289. Indonesia’s argument ignores the key limitation in Article 2.8 – namely, that the obligation to specify technical regulations on performance characteristics only applies where it is “appropriate” to do so. Thus, Indonesia’s argument fails to acknowledge that Article 2.8 – on its face – allows Members to structure their technical regulations based on design or descriptive characteristics when “appropriate.” As discussed above, Congress chose to structure Section 907(a)(1)(A) in terms of descriptive terms given that it is the additives, flavors, herbs, and spices that created the risk that Section 907(a)(1)(A) is intended to address. As such, it was

---

<sup>324</sup> Indonesia First Written Submission, para. 134.

<sup>325</sup> Indonesia First Written Submission, para. 136.



“appropriate” for Congress to structure Section 907(a)(1)(A) in terms of descriptive characteristics.

290. Moreover, it is Indonesia’s burden to establish a breach of Article 2.8. Yet, Indonesia does not even put forth a rationale why it is not “appropriate” to structure Section 907(a)(1)(A) in terms of descriptive characteristics. All Indonesia says is that it believes the definition of “characterizing flavor” is unclear.<sup>326</sup> This statement is both incorrect, and unrelated to the application of Article 2.8.

291. Because Indonesia has not and cannot demonstrate why it was “appropriate” to structure Section 907(a)(1)(A) in terms of performance rather than descriptive characteristics it has failed to meet its burden under TBT Article 2.8. While Indonesia does say that it believes the definition of “characterizing flavor” is unclear,<sup>327</sup> the United States fails to understand how such an argument is relevant to Article 2.8.

292. For the above reasons, the United States has acted consistently with TBT Article 2.8.

#### **H. Indonesia Has the Burden of Showing That the United States Acted Inconsistently With TBT Article 2.9**

293. Indonesia contends that the United States has acted inconsistently with TBT Article 2.9 by not notifying Section 907(a)(1)(A).<sup>328</sup> It is Indonesia’s burden to prove each element of its claim.

294. The United States would note that all relevant information regarding the measure has always been publicly available, and Indonesia did in fact provide input in the legislative process.

295. The United States further notes that it is a leader in supporting transparency among the WTO membership both generally and with regard to TBT measures specifically. The United States has notified 589 central and sub-central government measures to the TBT Committee since the creation of the WTO, and has notified 80 measures to the TBT Committee in 2010 alone. This is in direct contrast to Indonesia, which appears to have notified 46 measures total and only 14 measures in 2010. Further Indonesia has recently implemented a number of TBT measures without notifying them to the WTO that negatively impact an immense amount of U.S.

---

<sup>326</sup> See Indonesia First Written Submission, para. 135.

<sup>327</sup> See Indonesia First Written Submission, para. 135.

<sup>328</sup> Indonesia First Written Submission, paras. 137-142.

exports, and international trade generally.<sup>329</sup>

**I. Indonesia Has Not Shown that the United States Acted Inconsistently With TBT Article 2.12**

296. Indonesia argues that the United States acted inconsistently with the TBT Article 2.12 because it only provided a three month delay between publication of the FSPTCA and its entry of force.<sup>330</sup> Again, Indonesia’s argument is in error.

297. Article 2.12 states:

Except in those urgent circumstances referred to in paragraph 10, Members shall allow a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country members, to adapt their products or methods of production to the requirements of the importing Member.

298. Indonesia’s argument that the 90 day period provided by the United States was not reasonable is based on a TBT Committee decision, which states the following:

Subject to the conditions specified in paragraph 12 of Article 2 of the [TBT Agreement], the phrase “reasonable interval” shall be understood to mean *normally* a period a period of not less than 6 months, except when this would be ineffective in fulfilling the legitimate objectives pursued.<sup>331</sup>

299. Indonesia’s citation to this decision does not establish that the United States breached TBT Article 2.12 for numerous reasons. As a threshold matter, TBT Committee decisions are not part of the covered agreement and do not result in mandatory obligations on the Members. The Members are only bound by the text of the WTO Agreements themselves. The TBT Committee did not purport to amend the text of the TBT Agreement. Accordingly, Indonesia cannot simply assert that a non-mandatory Committee decision creates a binding obligation on another WTO Member.

300. Further, to the extent that the TBT Committee decision referenced by Indonesia provides

---

<sup>329</sup> Such measures include: Ministry of Trade Regulation 62/2009 and 22/2010 (labeling of food products); Decree No. Kep-99/MUI/III/2009 (halal certification requirements); and BPOM Regulation No. HK.00.05.1.23.3516 (distribution license requirements for certain drug products, cosmetics, food supplements, and food).

<sup>330</sup> Indonesia First Written Submission, paras. 144-145.

<sup>331</sup> TBT Committee, *Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995*, G/TBT/1/Rev.9, at para. 6 (September 8, 2008) (emphasis added).

relevant context, Indonesia still has not provided a breach of Article 2.12 because the six-month period provided for in the decision is qualified by the term “normally.” This indicates that a Member is not expected to provide a six month delay in all instances, but only that this “normally” should be the case. In other circumstances, the Committee decision clearly envisions that a different period may be appropriate. For example, the TBT Committee decision acknowledges that interval periods will be shorter than 6 months where delaying the entry into force would undermine the measure’s ability to fulfill the legitimate objective.

301. Given the fact that the TBT Committee decision does not bind the WTO membership, and given the qualified nature of its language, a panel’s determination of whether a particular delay is “reasonable” must be considered on a case by case basis. This conclusion is supported by the dictionary definition of the term “reasonable,” which is “in accordance with reason; not irrational or absurd.”<sup>332</sup> Thus, to determine whether a particular interval is reasonable, the Panel must weigh whether the interval provided is within reason or whether it is irrational or absurd, a determination that depends on all of the facts and circumstances surrounding the enactment of the measure.

302. In this instance, Indonesia has failed to meet its burden of demonstrating that the 90 day period provided by the United States is not reasonable. As the United States has discussed, the FSPTCA directly addresses a serious problem – youth smoking. Congress intended to limit this behavior as much as practicable. Indonesia fails to explain why delaying the effective date for six months would be consistent with the objectives of the measure.

303. In addition, Indonesia has adduced no evidence to suggest that the difference between a 90 day period and a 6 month period had any impact on the ability of Indonesian producers “to adapt their products or methods of production to the requirements of the importing Member.” Indonesian producers have been and are able, like all other cigarette producers, to market tobacco flavored and menthol-flavored cigarettes in the U.S. market. However, as far as the United States is aware, Indonesian producers, even *16 months* after the enactment of the FSPTCA have not adjusted their product lines to produce tobacco or menthol-flavored cigarettes. Thus, whether the United States waited three months or six months after the measure’s enactment to allow it to enter into force appears not to have affected Indonesian producers in any way.

304. For these reasons, Indonesia has failed to show that the United States has acted inconsistently with TBT Article 2.12.

**J. Indonesia Has Failed to Show That the United States Acted Inconsistently  
With TBT Article 12.3**

---

<sup>332</sup> *New Oxford English Dictionary*, vol. 2, at 2496 (1993). Exhibit US-82.

305. Indonesia argues that Section 907(a)(1)(A) is inconsistent with TBT Article 12.3.<sup>333</sup>

306. TBT Article 12.3 provides:

Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.

307. In order to establish a violation of Article 12.3, the complaining party must demonstrate the following: (1) that it is a developing country; (2) that the other Member did not take account of its special development, financial or trade needs during the preparation and application of a technical regulation; and (3) that the Member did not take account of these needs *with a view* to ensuring that the technical regulation does not create unnecessary obstacles to export.

308. Here, Indonesia has failed to meet its burden to prove any of these elements. Even assuming *arguendo* that Indonesia is a developing country, Indonesia has not demonstrated that the United States failed to take account of one or more special needs of Indonesia in the enactment of the FSPTCA. To the contrary, in the five years between the initial bill being introduced for consideration in the House of Representatives in 2004, and the law being enacted in 2009, Indonesia had ample opportunity to make its views known to both Congress and the Executive Branch and, in fact, did make its views known. As discussed above, Indonesia had numerous communications with both Congress and the Executive Branch, making the United States well aware of Indonesia's position. By allowing Indonesia an opportunity to comment on previous iterations of the legislation, as well as the version that was actually enacted into U.S. law, the United States complied with its obligations under Article 12.3.<sup>334</sup>

309. Finally, Indonesia failed to establish that the United States did not take account of its needs with a view to ensuring that Section 907(a)(1)(A) would not create an unnecessary obstacle to export. As a threshold matter, Article 12.3 only requires that Members take account of the needs of developing country Members in the "preparation and application" of a measure, "*with a view*" to ensuring that these measures do not create unnecessary obstacles to trade. The ordinary meaning of the phrase "with a view" is "with the aim of attaining or accomplishing" or "with the

---

<sup>333</sup> Indonesia First Written Statement, para. 147.

<sup>334</sup> In addition, an importing country Member does not violate Article 12.3 simply by not providing explanations of the measure to the satisfaction of the developing country Member, as Indonesia appears to argue. *See* Indonesia First Written Submission, para. 147 (concluding that the United States has acted in violation of Article 12.3 because "[t]he United States disregarded Indonesia's repeated concerns and never provided any justification for the measure or explained to Indonesia how it had complied with its obligations under [TBT] Article 2.5").

hope or intention of.”<sup>335</sup> In this sense, Article 12.3 does not require the developed country Member to accept every recommendation presented by the developing country Member but rather to proceed with the aim of ensuring that its measure does not create an unnecessary obstacle to exports. Indonesia concedes that it had both the opportunity to comment on the legislation and that Congress understood those comments.<sup>336</sup> The fact that Congress decided to value the public health over the interests of cigarette manufactures, both domestic and foreign, does not mean that the United States has acted inconsistently with Article 12.3.

310. Finally, Indonesia has failed to establish that Section 907 (a)(1)(A) creates an unnecessary obstacle to export. For the reasons the United States discussed above regarding TBT Article 2.2, the U.S. measure does not create an unnecessary obstacle measure to export and therefore does not violate TBT Article 12.3 on this basis either.

#### **K. Section 907(a)(1)(A) Is Justified Under Article XX**

311. As the United States has discussed, Indonesia has failed to establish that Section 907(a)(1)(A) breaches U.S. obligations under GATT Article III:4. Should the Panel reach the issue of GATT exceptions, the application of Section 907(a)(1)(A) would be justified under GATT Article XX(b).

312. GATT Article XX(b) provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

....

(b) necessary to protect human, animal, or plant life or health...

313. To justify a measure under Article XX(b), the Appellate Body has previously explained that the responding party must demonstrate that the measure: (1) falls under the scope of the Article XX(b) exception; and (2) satisfies the requirements of the Article XX chapeau.<sup>337</sup>

314. In this instance, Section 907(a)(1)(A) falls under the scope of Article XX(b) since the

---

<sup>335</sup> *New Shorter Oxford English Dictionary*, vol 2, at 3578 (1993). Exhibit US-83.

<sup>336</sup> See Indonesia First Written Submission, paras. 24-27 (noting that Indonesia had numerous communications with Administration officials and Congressional members and that the trade implications of Section 907(a)(1)(A) were raised within the U.S. Government.

<sup>337</sup> See, e.g., *US – Gasoline (AB)*, at 22; *US – Shrimp (AB)*, paras. 119-120.

measure was necessary to protect human life and health from the risk posed from smoking. In addition, the measure is consistent with the Article XX chapeau as it is “not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail” nor is it “a disguised restriction on international trade.” Therefore, Section 907(a)(1)(A) would be justified under Article XX.

**1. Section 907(a)(1)(A) Falls Within the Scope of the Article XX(b) Exception**

315. Past panels have indicated that two elements must be met for a measure to fall under the scope of the Article XX(b) exception: (1) the policy in respect of the measure for which the provision is invoked must fall within the range of policies designed to protect human, animal or plant life or health; and (2) the inconsistent measure for which the exception is invoked must be necessary to fulfil the policy objective.<sup>338</sup>

316. As discussed in section III.H, Section 907(a)(1)(A) was enacted in order to protect human life and health from the risk posed by smoking. Further, Section 907(a)(1)(A) was necessary to ensure that products that are predominantly used as “starter” products by youth, leading to years of addiction, health problems, and possibly death, cannot be sold in the United States at all.

**(a) Section 907(a)(1)(A) Pursues a Policy Objective of Protecting Human Life and Health**

317. To determine whether a measure pursues a policy objective of protecting human life and health, the Panel should first consider whether a risk to human life and health exists. If a risk is found to exist, the Panel should next determine whether the policy objective underlying the measure is to reduce that risk. If so, the Panel should conclude that the measure’s policy falls within the range of policies designed to protect human life or health in accordance with Article XX(b).

318. As elaborated above, this is clearly the case here. Smoking presents an undeniable risk to human life and health. And by banning certain products that are predominantly used as smoking “starter” products by young smokers, Congress clearly took action to reduce this risk of smoking.

**(b) Section 907(a)(1)(A) Is Necessary to Protect Human Life and Health**

319. Section 907(a)(1)(A) is necessary to protect human life and health from the identified risk.

---

<sup>338</sup> See, e.g., *Brazil – Tyres (Panel)*, para. 7.40; *EC – Asbestos (Panel)*, para. 8.169.

320. In determining the meaning of the word “necessary,” the Panel should apply the ordinary meaning of the term, which the Appellate Body described as follows:

The word “necessary” normally denotes something “that cannot be dispensed with or done without, requisite, essential, needful”. We note, however, that a standard law dictionary cautions that:

[t]his word must be considered in the connection in which it is used, as it is a word susceptible of various meanings. It may import absolute physical necessity or inevitability, or it may import that which is only convenient, useful, appropriate, suitable, proper, or conducive to the end sought. It is an adjective expressing degrees, and may express mere convenience or that which is indispensable or an absolute physical necessity.<sup>339</sup>

321. Contrary to Indonesia’s contention, the ordinary meaning of “the word ‘necessary’ is not limited to that which is ‘indispensable’ or ‘of absolute necessity’ or ‘inevitable.’”<sup>340</sup>

322. As has been detailed in this submission, smoking poses a severe risk to human life and health, and the FSPTCA is the latest in a series of restrictions placed on the cigarette companies to address this risk. With regard to the particular problem of youth smoking, many of these previous measures limited advertising that targeted youth. However, Congress properly found that the rates of youth smoking remained too high, and something more comprehensive was needed. In this regard, Section 907(a)(1)(A)’s prohibition of certain products that are best described as “starter” cigarettes was necessary to protect human life and health.

323. The United States believes the Panel should reach the same conclusion if it follows the method used by past panels to determine whether a measure is necessary under one of the Article XX exceptions. When faced with the question of whether a measure is necessary, other panels have engaged in “a process of weighing and balancing a series of factors,” which include (1) the importance of the interests or values at stake; (2) the contribution made by the measure to its objective; and (3) the trade restrictiveness of the measure.<sup>341</sup> All three of these factors weigh in favor of a determination that Section 907(a)(1)(A) was necessary to protect human life and health from the risks posed by smoking, particularly youth smoking.

324. First, one factor panels generally examine to determine whether a measure is necessary is the importance of the interests or values at stake. If the interest at stake is of fundamental

---

<sup>339</sup> *Korea – Beef (AB)*, para. 160.

<sup>340</sup> *Compare Korea – Beef (AB)*, para. 161, with *Indonesia First Written Submission*, para. 103.

<sup>341</sup> *Brazil – Tyres (AB)*, para. 178.

importance, past panels have been more inclined to determine that a measure is necessary to achieve its stated objective.<sup>342</sup> Such is the case here. The United States is applying Section 907(a)(1)(A) for the protection of the life and health of its population, particularly the protection of its youth.

325. Second, to determine whether a measure is necessary to achieve a certain objective, panels have weighed the measure’s contribution to the achievement of that objective. A contribution exists when there is a genuine relationship of the ends and means between the objective pursued and the measure at issue.<sup>343</sup> As before, if a panel finds a genuine relationship between the measure and the policy goal it intends to pursue, panels are more inclined to consider the measure in question necessary.<sup>344</sup>

326. A consideration of this second factor also weighs heavily in favor of a determination that Section 907(a)(1)(A) was necessary to achieve its objective. Section 907(a)(1)(A) is directly contributing to the protection of human life and health by ensuring products that present a particular risk to youths cannot be sold on the market.

327. Third, to decide whether a measure is necessary to achieve its stated objective, panels have considered the measure’s trade restrictiveness. The more restrictive a measure is, the more carefully it may need to be reviewed to determine whether it is necessary to achieve a particular objective. However, a restrictive measure may still be considered necessary based on the context of the situation in which the Article XX(b) defense is invoked.<sup>345</sup>

328. The context here, as explained above, is that youth smoking rates remained unacceptably high at the time of the FSPTCA’s enactment and Congress found it appropriate to apply more severe restrictions than had been applied up to this date.

329. Thus, like the other two factors, the limited trade restrictiveness of the measure also favors a determination that Section 907(a)(1)(A) was necessary to protect human life and health. As a result, Section 907(a)(1)(A) meets the requirements of the Article XX(b) exception.

## **2. Section 907(a)(1)(A) Meets the Requirements of the GATT 1994 Article XX(b) Chapeau**

---

<sup>342</sup> *EC – Asbestos (AB)*, para. 172.

<sup>343</sup> *Brazil – Tyres (AB)*, para. 145.

<sup>344</sup> *See Brazil – Tyres (AB)*, para. 151.

<sup>345</sup> *See US – Gambling (AB)*, para. 323 (noting that it was appropriate for the panel in the dispute to downplay the trade restrictiveness of the measure in question given the specific context in which the measure was enacted).



330. To justify a measure under GATT 1994 Article XX(b), the Appellate Body has explained that the responding party must also show that the measure meets the requirements of the Article XX chapeau.<sup>346</sup>

331. Specifically, the chapeau prohibits a measure from being “applied in a manner which would constitute a means of arbitrary and unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on international trade ...”. Thus, to meet the requirements of the chapeau, past Appellate Body reports have explained that the responding party must demonstrate that its measure (1) is not a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail; or (2) a disguised restriction on international trade.<sup>347</sup>

332. As the United States will demonstrate below, Section 907(a)(1)(A) meets the requirements of the Article XX chapeau.

**(a) Section 907(a)(1)(A) is Not a Means of Arbitrary or  
Unjustifiable Discrimination Between Countries Where the  
Same Conditions Prevail**

333. Previous Appellate Body reports have explained that a measure will be considered to be applied in a manner that results in arbitrary or unjustifiable discrimination if three conditions are met: (1) the application of the measure results in discrimination; (2) the discrimination is arbitrary or unjustifiable in character; and (3) the discrimination occurs between countries where the same conditions prevail.<sup>348</sup> In the instant dispute, these conditions are not met.

334. First, there is no differential treatment at all, and therefore cannot be any “discrimination,” arbitrary, unjustified, or otherwise. As discussed above, the measure at issue is facially neutral measure that applies equally to all cigarette products, regardless of origin.

335. However, even if Section 907(a)(1)(A) is found to “discriminate,” such conduct could not be considered “arbitrary” or “unjustified.” The *New Shorter Oxford English Dictionary* defines “arbitrary” as “based on mere opinion or preference as opp. to the real nature of things; capricious, unpredictable, inconsistent.”<sup>349</sup> Likewise, “unjustifiable” is defined as “not

---

<sup>346</sup> See, e.g., *US – Gasoline (AB)*, p. 22; *US – Shrimp (AB)*, paras. 119-120.

<sup>347</sup> See *Brazil – Tyres (Panel)*, para 7.225 (noting that the panel frequently considers “arbitrary” and “unjustifiable” discrimination together “in light of the close relationship between them”). The Panel in *Brazil – Tyres* also noted that this approach was followed in the Appellate Body Report on *US – Gasoline*, the Appellate Body Report in *US – Gambling*, and the Panel Report on *EC – Asbestos*, among others.

<sup>348</sup> *Brazil – Tyres (AB)*, para. 215.

<sup>349</sup> See *New Shorter Oxford English Dictionary*, at 107 (1993). Exhibit US-84.

justifiable, indefensible.”<sup>350</sup> In a similar fashion, past panel reports have required that in order for the responding party to show that any discrimination or differential treatment to a particular country is not “arbitrary or unjustifiable,” it must show that its action is not “capricious or random.”<sup>351</sup> The panel in *Brazil – Tyres* also noted that the question of whether this element is met should focus “on the cause of the discrimination, or the rationale put forward to explain its existence.”<sup>352</sup> Thus, if a responding party provides a rationale for the measure that is not capricious, random, or indefensible, the measure will not run afoul of this element of the chapeau.

336. Here, that is clearly the case. As the United States has explained in great detail, the line Congress drew in deciding what products would be banned and what products would not was without question not an arbitrary or capricious one. Rather, it was one grounded in the evidence and tailored to address a specific public health risk.

337. As such, Section 907(a)(1)(A) does not amount to an arbitrary or unjustified act of discrimination.

**(b) Section 907(a)(1)(A) Is Not a Disguised Restriction on  
International Trade**

338. The final requirement for a measure to be justified under the chapeau and GATT Article XX(b) is that it must not be a disguised restriction on international trade. An examination of a measure’s purpose to determine whether it has “protectionist objectives” is relevant to this issue.<sup>353</sup> If a measure’s purpose is protectionist in nature, it will likely be considered a disguised restriction on trade and will not meet the requirements of the chapeau.

339. In this instance, the evidence demonstrates that Section 907(a)(1)(A) is not a disguised restriction on trade.

340. As a general matter, the evidence clearly demonstrates that the FSPTCA is an *anti-smoking* law. In no way is it intended to benefit, nor does it in fact benefit, cigarette companies. There is not one shred of evidence that U.S. companies will or even could benefit from the law’s severe curtailing of their business practices.

341. The same point applies equally to Section 907(a)(1)(A). Although the measure results in

---

<sup>350</sup> See *New Shorter Oxford English Dictionary*, at 3493 (1993). Exhibit US-85.

<sup>351</sup> *Brazil – Tyres (AB)*, para. 232.

<sup>352</sup> *Brazil – Tyres (AB)*, para. 226.

<sup>353</sup> See *EC – Asbestos (Panel)*, para. 8.238.

the banning of Indonesia’s clove cigarettes, U.S. companies are also prohibited by statute from developing an entire product line to attract new smokers. In fact, there is no evidence that Congress’s purpose in enacting Section 907(a)(1)(A) had anything to do with imports at all.<sup>354</sup> Rather, the HR Report clearly indicates a concern with the products that U.S. companies were selling. The fact that foreign companies made products that posed the same risks and were likewise affected by the measure cannot make the measure a protectionist one. And this one is not.

342. Accordingly, Section 907(a)(1)(A) meets the requirements of the chapeau and is justified under GATT Article XX(b).

**L. The United States Has Not Nullified or Impaired Benefits Accruing Directly or Indirectly to Indonesia**

343. As the United States has acted consistently with its GATT and TBT Agreement obligations, it has thus not nullified or impaired benefits accruing directly or indirectly to Indonesia.

**V. CONCLUSION**

344. For the foregoing reasons, the United States respectfully requests that the Panel reject Indonesia’s claims in their entirety.

---

<sup>354</sup> See HR Rep’t, at 37, Exhibit US-67 (making explicit reference to the RJ Reynolds’ brands “Mandalay Lime” and “Warm Winter Toffee” and the Brown & Williamson brands “Midnight Berry” and “Mocha Taboo”); see also section III.E(3) (explaining all the flavored brands that the U.S. companies produced prior to the enactment of the FSPTCA).

### LIST OF EXHIBITS

- US-1 U.S. Surgeon General, *Reducing Tobacco Use*, at 30 (2000), Chapter 2
- US-2 Centers for Disease Control and Prevention (“CDC”), *Adult Cigarette Smoking in the United States: Current Estimate*, (CDC, *Adult Cigarette Smoking in the United States*)
- US-3 Dep’t of Health and Human Services, Proposed Rule on Required Warnings of Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524 (November 12, 2010)
- US-4 CDC, *Youth Risk Behavior Surveillance – United States, 2009*, MMWR, Vol 59, No. SS-5, at 10 (June 4, 2010), [cdc.gov/mmwr/pdf/ss/ss5905.pdf](http://cdc.gov/mmwr/pdf/ss/ss5905.pdf)
- US-5 *2007 National Survey on Drug Use and Health* (“NSDUH”), Vol. I Summary of National Findings, at Table 4.10A
- US-6 CDC, “Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses-United States, 2000-2004,” MMWR 57(45):1226-1228 (November 14, 2008)
- US-7 Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-3121, 123 Stat. 1776
- US-8 CDC, “Cigarette Smoking-Attributable Morbidity – United States, 1999-2000,” MMWR 52(35), at 842 (September 5, 2003), <http://www.cdc.gov/mmwr/PDF/wk/mm5235.pdf>
- US-9 CDC, *The Health Consequences of Smoking: A Report of the Surgeon General, 2004* (2004), Chapter 1
- US-10 Zhang, X., *et al.*, “Cost of Smoking to the Medicare Program, 1993,” *Health Care Financing Review*, 20(4) (Summer 1999)
- US-11 Rumberger, *et al.*, *Potential Costs and Benefits of Smoking Cessation in the United States* (April 30, 2010)
- US-12 Wilson and Belford, “Indonesia Resists the Anti-Smoking Tide Elsewhere,” *NY Times*, at A6 (November 14, 2010)
- US-13 CDC, “Cigarette Smoking Among Adults and Trends in Smoking Cessation-United States, 2008,” MMWR 58(44):1227-32 (November 13, 2009)

<http://www.cdc.gov/mmwr/PDF/wk/mm5844.pdf>

- US-14 CDC, “Cigarette Use Among High School Students – United States, 1991-2009,” MMWR 59(26):797-801 (July 9, 2010)  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm>
- US-15 Data Drawn from the *2007 National Survey on Drug Use and Health*
- US-16 *Youth and Tobacco: Preventing Tobacco Use among Young People: A Report of the Surgeon General*, Table 7 at 49 (1994),  
[http://sgreports.nlm.nih.gov/NN/B/C/L/Q/\\_/nnbclq.pdf](http://sgreports.nlm.nih.gov/NN/B/C/L/Q/_/nnbclq.pdf)
- US-17 CDC, *Sustaining State Programs for Tobacco Control: Data Highlights 2006*, Table 1 at 11,  
[http://www.cdc.gov/tobacco/data\\_statistics/state\\_data/data\\_highlights/2006/index.htm](http://www.cdc.gov/tobacco/data_statistics/state_data/data_highlights/2006/index.htm)
- US-18 Lindsay, “Psychosocial and Pharmacological Explanations of Nicotine’s ‘Gateway Drug’ Function,” *Journal of School Health*, vol 67, No. 4, at 123 (April 1997)
- US-19 Evans, *et al.*, “Influence of Tobacco Marketing and Exposure to Smokers on Adolescent Susceptibility to Smoking,” *Journal of the National Cancer Institute* (October 1995)
- US-20 Pierce JP, *et al.*, “Tobacco Industry Promotion of Cigarettes and Adolescent Smoking,” *Journal of the American Medical Assoc.*, 279(7):511-505 (February 1998) [with erratum in *JAMA* 280(5):422 (August 1998)]
- US-21 DiFranza, JR, *et al.*, “Initial Symptoms of Nicotine Dependence in Adolescents,” *Tobacco Control* 9, at 317 (September 2000)
- US-22 DiFranza, *et al.*, “Symptoms of Tobacco Dependence After Brief Intermittent Use,” *Archives of Pediatric and Adolescent Medicine* 161(7) (July 2007)
- US-23 CDC, “High School Students Who Tried to Quit Smoking Cigarettes – United States, 2007,” MMWR 58(16) (May 1, 2009)
- US-24 *Factors Associated with Successful Smoking Cessation in US, 2000*, *American Journal of Public Health*, Vol. 97, Iss. 8 (2007)
- US-25 61 Fed. Reg. 44396 (August 28, 1996)
- US-26 Hing, *Visits to Primary care Delivery Sites: United States, 2008*, NCHS Data

- Brief, at 1 (October 2010), <http://www.cdc.gov/nchs/data/databriefs/db47.pdf>
- US-27 *Department of the Treasury Report to Congress on Federal Tobacco Receipts Lost Due To Illicit Trade and Recommendations for Increased Enforcement* (February 4, 2010), <http://www.ttb.gov/pdf/tobacco-receipts.pdf>,
- US-28 Pappas, *et al.*, “Cadmium, lead, and thallium in smoke particulate from counterfeit cigarettes compared to authentic US brands,” *Food and Chemical Toxicology*, Vol. 45, Issue 2 (February 2007)
- US-29 U.S. Federal Trade Commission, *Cigarette Report for 2006*, at Table 1A (2009)
- US-30 Phillip Gardiner, “The African Americanization of menthol cigarette use in the United States,” *Nicotine & Tobacco Research*, Vol. 6, Supp. 1, at S55 (February 2004)
- US-31 Cigarettes: Domestic and Imported, 2000-2009
- US-32 Market Share Data (drawn from the following sources: Philip Morris USA, *Cigarette Brand Market Share*, [http://www.philipmorrisusa.com/en/cms/Company/Market\\_Information/default.aspx](http://www.philipmorrisusa.com/en/cms/Company/Market_Information/default.aspx); Reynolds American Inc., *Investor Fact Sheet*, <http://www.reynoldsamerican.com/invest.cfm>; Lorillard, Inc., *SEC Form 10-Q Quarterly Report for the Quarterly Period Ended September 30, 2010* <http://investors.lorillard.com/phoenix.zhtml?c=134955&p=irol-sec>
- US-33 Jane Lewis and Olivia Wackowski, “Dealing with an Innovative Industry: A Look at Flavored Cigarettes Promoted by Mainstream Brands,” *American Journal of Public Health*, Vol. 96, No. 2 (February 2006)
- US-34 See Philip Morris USA Inc., *Written Submission to the Food and Drug Administration’s Tobacco Products Scientific Advisory Committee on Use of Menthol in Cigarettes*, at 13 (June 30, 2010)
- US-35 American Lung Association, Tobacco Policy Trend Alert, *From Joe Camel to Kauai Kolada – the Marketing of Candy-Flavored Cigarettes*, at 1 (July 2005, updated May 2006), <http://slati.lungusa.org/reports/CandyFlavoredUpdatedAlert.pdf>,
- US-36 Caraballo, *Menthol and Demographics* (March 30, 2010)
- US-37 CDC, “Epidemiologic Notes and Reports Illnesses Possibly Associated with Smoking Clove Cigarettes,” *MMRW Weekly*, 34(21), 297-9 (May 31, 1985)

- US-38 Guidotti, *et al.*, “Clove Cigarettes: the Basis for Concern Regarding Health Effects,” *The Western Journal of Medicine* (August 1989)
- US-39 Demirtas, “Djarum Cigarettes & Cigars,” <http://www.demirtas.com.tr/Djarum.htm>
- US-40 Carrie M. Carpenter, *et al.*, “New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies,” *Health Affairs*, Vol. 24, No. 6 (Nov./Dec. 2005)
- US-41 Guidotti & Laing, “Clove Cigarettes,” *The Western Journal of Medicine* (August 1992)
- US-42 Susan Farrer, “Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes,” *National Institute on Drug Abuse (“NIDA”)*, Vol. 18, No. 2 (August 2003)
- US-43 Committee on Substance Abuse, “Hazards of Clove Cigarettes,” *Pediatrics*, Vol 88, (1991)
- US-44 Malson, *et al.*, “Clove Cigarette Smoking: Biochemical, Physiological, and Subjective Effects,” *Pharmacology Biochemistry and Behavior* 74(3): 739-45 (February, 2003)
- US-45 Polzin, *et al.*, “Determination of eugenol, anethole, and coumarin in the mainstream cigarette smoke of Indonesian clove cigarettes,” *Food & Chemical Toxicology* 45(10): 1948-53 (October 2007)
- US-46 Stanfill SB, Brown CR, Yan XJ, Watson CH, Ashley DL, “Quantification of Flavor-Related Compounds in the Unburned Contents of Bidi and Clove Cigarettes,” *J. Agric. Food Chem.* 2006, 54, 8580-8588.
- US-47 Guidotti, *et al.*, “Clove Cigarettes: Development of the Fad and Evidence for Health Effects,” *Current Topics in Pulmonary Pharmacology and Toxicology*, Vol. 2
- US-48 CDC, *Men and Young Adults Most Likely Multi-Product Tobacco Users* (Aug 9, 2010), [http://www.consumeraffairs.com/news04/2010/08/tobacco\\_use.html](http://www.consumeraffairs.com/news04/2010/08/tobacco_use.html)
- US-49 Substance Abuse and Mental Health Services Admin., *National Household Survey on Drug Abuse, 2001*, Vol. 1, Ch. 4.  
<http://oas.samhsa.gov/nhsda/2k1nhsda/vol1/chapter4.htm#4.spec>
- US-50 American Lung Association, Tobacco Policy Trend Alert Addendum,

*Alcohol-Flavored Cigarettes – Continuing the Flavored Cigarette Trend* (May 2006), <http://slati.lungusa.org/alerts/Alcohol-Flavored-Addendum.pdf>

- US-51 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 1211 (July 2008)
- US-52 ACNielsen 2008 Data on Flavored Cigarettes in the United States
- US-53 FDA Survey Assessment (Klein Article, National Youth Tobacco Survey, Monitoring the Future, and the National Survey on Drug Use and Health)
- US-54 “Tobacco Use Among Middle and High School Students – United States, 200-2009,” *MMWR*, Vol. 59, No. 33, 1063-1068 (August 27, 2010)
- US-55 Gfroerer, *et al.*, “Prevalence of youth substance use: the impact of methodological differences between two national surveys,” *Drug and Alcohol Dependence*, vol. 47 (1997)
- US-56 NSDUH 2002 Clove Tables
- US-57 NSDUH 2003 Clove Tables
- US-58 *Smoking and Health: The Report of the Advisory Committee to the Surgeon General of the Public Health Service*, U.S Department of Health, Education, and Welfare, Public Health Service Pub. No. 1103, Part I (1964)
- US-59 Master Settlement Agreement among U.S. tobacco companies and Attorneys General of the United States
- US-60 *Tobacco Control in the Wake of the 1998 Settlement Agreement*, Steven A. Schroeder, *N. Engl. J. Med.*, 350;3 (January 15, 2004).
- US-61 2006 Consent Agreement between RJ Reynolds and Attorneys General of the United States
- US-62 Examples of Cigarettes Certified for Sale in the United States as of 2009
- US-63 New York List of Fire-Safe Certified Cigarettes as of January 20, 2009
- US-64 Maine List of Fire-Safe Certified Cigarettes as of July 29, 2009
- US-65 United States v. Philip Morris USA, Inc., et al., No. 99-CV-02496GK (U.S. Dist.



- Ct., D.C.), Final Opinion, August 17, 2006
- US-66 *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000)
- US-67 H.R. Rep. No. 111-58, Pt. 1 (2009)
- US-68 P.L. 111-117, 123 Stat. 3151, sec. 510 (December 16, 2009)
- US-69 World Health Organization, Framework Convention on Tobacco Control, 23 June 2003, Article 16, I.L.M. 518
- US-70 World Health Organization, International Agency for Research on Cancer. Tobacco smoke and Involuntary Smoking. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 83
- US-71 Stanfill SB, Ashley DL, “Solid phase microextraction of alkenylbenzenes and other flavor-related compounds from tobacco for analysis by selected ion monitoring gas chromatography-mass spectrometry” *J Chromatogr. A* 858(1999):79-89
- US-72 Stanfill S, Duncan B, Yan X, Richter P, Watson CH, “Levels of 18 flavor analytes present in non-mentholated, mentholated and clove cigarettes products,” 2010
- US-73 Kreslake, JM, et al., “The Menthol Smoker: Tobacco industry research on consumer sensory perception of menthol cigarettes and its role in smoking behavior,” *Nicotine & Tobacco Research* 10(4), April 2008
- US-74 Ministry of Finance Regulations No. 181/PMK.011/2009 and No. 99/PMK.011/2010
- US-75 World Atlas Report on Indonesian Cigarette Exports 2001-2009
- US-76 Change in Domestic and Imported Cigarette Sales Before and After September 2009
- US-77 *New Shorter Oxford English Dictionary*, vol 2, at 2569 (1993)
- US-78 *New Shorter Oxford English Dictionary*, vol 2, at 1895 (1993)
- US-79 Letter from Peter D. Sutherland, Director-General of the GATT, to Ambassador John Schmidt, Chief U.S. Negotiator (December 15, 1993)
- US-80 U.S. Third Party Submission in *EC – Asbestos*

- US-81 Letter to Ambassador Zoellick (Jan. 23, 2004); Letter to Senator Kennedy (January 29, 2007); Letter to Ambassador Schwab (August 28, 2007); Letter to Ambassador Schwab (May 28, 2008); Letter to Speaker of the House Pelosi (July 25, 2008); Letter to Acting USTR Peter Allgeier (January 29, 2009)
- US-82 *New Oxford English Dictionary*, vol. 2, at 2496 (1993)
- US-83 *New Shorter Oxford English Dictionary*, vol 2, at 3578 (1993)
- US-84 *New Shorter Oxford English Dictionary*, at 107 (1993)
- US-85 *New Shorter Oxford English Dictionary*, at 3493 (1993)
- US-86 “New, More Graphic Cigarette Labels Unveiled,” *Washington Post*, November 10, 2010
- US-87 See *2009 National Survey on Drug Use and Health*, Volume I. Summary of National Findings,  
<http://www.oas.samhsa.gov/NSDUH/2k9NSDUH/2K9Results.htm>