

*United States – Measures Affecting the  
Production and Sale of Clove Cigarettes*

**(AB-2012-1 / DS406)**

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## **I. Introduction**

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The seven public health organizations signing below submit this amicus curiae because we believe that Section 907 (a)(1)(A) of the Family Smoking Prevention and Tobacco Control Act of 2009 (“FSPTCA”) addresses a serious public health problem with a specific impact on children in the United States and should not be found to violate any international trade agreements. The FSPTCA is designed to deal with the devastating effects of cigarette smoking, one of this country’s most serious public health problems. This problem is by no means unique to the United States. Worldwide, cigarette smoking represents one of the largest preventable causes of death and disease. In fact, globally, tobacco use causes more than 5 million deaths per year, and current trends show that tobacco use will cause more than 8 million deaths annually by 2030.<sup>1</sup> Smoking is the leading preventable cause of premature death in America, causing over 400,000 deaths in the United States each year.<sup>2</sup> The rulings made by this body regarding tobacco control legislation will thus have important implications for all nations in their efforts to deal with the tobacco epidemic. A ruling that the provision at issue in this case violates international trade agreements would seriously compromise the ability of all nations to enact legitimate public health measures to protect their citizens.

The FSPTCA provides a comprehensive national regulatory structure applicable to many different aspects of the tobacco products market and designates the U.S. Food and Drug Administration (“FDA”) as the central federal agency with regulatory jurisdiction over tobacco products. The statutory provision at issue here—a broad prohibition on the sale of flavored cigarettes—is one of many in the statute designed to prevent young people from initiating tobacco usage. The provision should be evaluated within the broader context of the overall legislation, its goals and its impact. The evidence before the U.S. Congress at the time the statute was enacted demonstrated that the cigarettes at issue were sold disproportionately to children and that their primary impact in the market was to facilitate youth initiation and addiction. Removing such cigarettes from the market clearly protects an important public health interest.

A central purpose of the FSPTCA is to give the U.S. government broad power to restrict the sale of any cigarettes that appeal to children, including the authority to prohibit or restrict the sale of cigarettes with menthol as their characterizing flavor (“menthol cigarettes”) as well as any other flavoring that FDA later determines increases youth tobacco use. In contrast to other flavorings covered by FSPTCA Section

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<sup>1</sup> World Health Organization. WHO Report on the Global Tobacco Epidemic, 2008.  
<http://www.who.int/tobacco/mpower/2009/en/index.html>

<sup>2</sup> FSPTCA, Public Law 111-31, June 22, 2009 at Sec. 2, Finding 13 [21 U.S.C. 387 note].

907(a)(1)(A), which had a very small market share at that time and were regularly smoked by very few smokers, menthol cigarettes have a very large market share (approximately 27% of the United States cigarette market) and are regularly smoked by more than 12 million Americans.<sup>3</sup> Although menthol cigarettes constitute a major public health problem in the United States, Congress's conclusion that prohibition of a product with so large a market share and with so many regular users – adults as well as youth – raises issues that are not presented by products with far fewer regular users should not be second guessed by an international trade body. Moreover, a nation seeking to address such an important public health problem should be able to do so without fear of a challenge under international trade agreements.

This brief will explain why the provisions of the FSPTCA regarding both menthol cigarettes and other flavored cigarettes are not inconsistent with the U.S. trade obligations under the *Agreement on Technical Barriers to Trade*. Rather, the provisions represent a good faith effort by the U.S. Congress to address a complex, but critically important public health issue based on legitimate public health considerations without discriminatory intent or effect in light of the different public health problems these two categories of cigarettes present. Both sets of provisions provide important protection to the public health. Developing regulatory policies to protect public health against a product as uniquely harmful as tobacco presents many vexing challenges. In developing long-term, comprehensive solutions to this problem and protecting the health of their citizens, governments must be able to make reasonable distinctions, take incremental steps and implement policies that take into account the unique circumstances within their borders without being subjected to challenge under international trade agreements. The issues presented by this case are significant for all governments seeking to establish regulatory regimes for the protection of the public health of their citizens.

## **II. The Family Smoking Prevention and Tobacco Control Act (“FSPTCA”) Addresses a Serious Public Health Challenge That Disproportionately Affects Children**

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A. Cigarette smoking is the leading preventable cause of premature death in the United States, and prevention of smoking initiation by young people is a critical strategy to deal with this problem

The FSPTCA was enacted to protect the public health against death and disease caused by tobacco products. Smoking is the leading preventable cause of premature death in America, causing over 440,000 deaths in the United States each year. In addition, approximately 8.6 million Americans suffer from chronic

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<sup>3</sup> U.S. Federal Trade Commission (FTC), “Cigarette Report for 2004 and 2005,” Table 7 (2007), <http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf>. Also based on data in 2006 National Health Interview Survey.

illnesses related to smoking.<sup>4</sup> Despite the numerous reports of the Surgeon General and educational campaigns on the health risks of smoking, more than 45 million U.S. adults still smoke, and nearly one in five high school students are current smokers.<sup>5</sup> The large majority of American tobacco users begin using such products while in their teens and become addicted to these products before reaching the age of 18.<sup>6</sup> Unfortunately, declines in youth smoking rates have stalled in recent years, and young people continue to start to smoke.<sup>7</sup> Each day in the United States, nearly 4,000 young people under the age of 18 try their first cigarette, and an additional 1,000 become new regular, daily smokers.<sup>8</sup> Approximately half of those who become regular smokers will die from smoking-related disease.<sup>9</sup>

The presence of nicotine in cigarettes makes smoking highly addictive. Many young people underestimate their own vulnerability to nicotine and become addicted to cigarettes while they believe they are still only experimenting with smoking. Once they are addicted, they find it very difficult to quit. While 69 percent of current smokers want to stop smoking completely, because of the addictive power of nicotine, most smokers fail when they try to quit smoking.<sup>10</sup> The evidence demonstrates that young people who do not begin smoking by the time they reach 18 are unlikely ever to become smokers.<sup>11</sup> Thus, preventing young people from beginning to smoke before they reach the age of 18 has a very large impact on the public health. Preventing smoking initiation, especially of young people, is a priority public health objective in the United States. The FSPTCA was designed to provide a regulatory structure to further this goal.

#### B. One key objective of FSPTCA was to reduce smoking initiation among young people

The FSPTCA is not the first law enacted by the U.S. to curb tobacco use, particularly among young people.<sup>12</sup> Indeed, tobacco control efforts in the U.S. reflect a step-by-step incremental process of which the FSPTCA is only the latest action. The U.S. enacted its first health warnings on cigarettes in 1965.

<sup>4</sup> FSPTCA, Public Law 111-31, June 22, 2009 at Sec. 2, Finding 13 [21 U.S.C. 387 note].

<sup>5</sup> CDC, "Vital Signs: Current Cigarette Smoking Among Adults Aged ≥ 18 Years - United States, 2005-2010," *MMWR* 60(35):1135-1140, September 9, 2011. CDC, "Youth Risk Behavior Surveillance, United States, 2009," *MMWR* 59(SS-5), June 4, 2010.

<sup>6</sup> FSPTCA, Public Law 111-31, June 22, 2009 at Sec. 2, Finding 31 [21 U.S.C. 387 note].

<sup>7</sup> CDC, Youth Risk Behavior Surveillance.

<sup>8</sup> Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, *Results from the 2010 National Survey on Drug Use and Health, NSDUH: Summary of National Findings*, 2011. <http://oas.samhsa.gov/NSDUH/2k10NSDUH/tabs/Sect4peTabs10to11.pdf>

<sup>9</sup> U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking. A Report of the Surgeon General*, 2004 <http://www.surgeongeneral.gov/library/smokingconsequences/>.

<sup>10</sup> CDC, "Quitting Smoking Among Adults Aged - United States, 2001-2010," *MMWR* 60(44):1513-1519, November 11, 2011.

<sup>11</sup> U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking. A Report of the Surgeon General*, 2004

<sup>12</sup> See, e.g., FSPTCA, Public Law 111-31, June 22, 2009 at Sec. 2, Findings, and Sec. 3, Purposes [21 U.S.C. 387 note].

Since that time it has held numerous hearings that examined factors that contribute to youth tobacco use and has adopted a series of laws intended to curb youth tobacco use. When it enacted the FSPTCA in 2009, Congress found that each of those increasingly strong measures had not solved the problem and that more needed to be done. During Congress's deliberations, some of the most prestigious independent organizations, such as the Institute of Medicine of the U.S. National Academy of Sciences and the U.S. President's Cancer Panel reached the same conclusion and adopted recommendations consistent with the provisions of the FSPTCA. Thus, the U.S. Congress based the FSPTCA on an overwhelming scientific record.

When it enacted the FSPTCA in 2009, the Congress identified its objectives.<sup>13</sup> Among these objectives is the prevention of smoking initiation by young people. The Act provides an array of regulatory measures designed to achieve this and related objectives identified in the statute. The Act directs the FDA to promulgate a wide range of restrictions on the advertising, promotion and marketing of cigarettes and smokeless tobacco products, and gave the FDA broad regulatory authority over all tobacco products. Congress found that the regulatory provisions it enacted were necessary because previous efforts to restrict manufacture, sale, advertising and marketing of tobacco products had failed to adequately curb tobacco use by adolescents. It therefore concluded that additional restrictions on the sale, promotion, and distribution of such products were needed to reduce smoking initiation by young people.<sup>14</sup>

The statutory findings, the statement of statutory purpose, and the operative provisions of the statute all demonstrate the intention of the Congress to promote public health through regulatory measures designed to discourage smoking initiation and to encourage existing users to quit. As Congress specifically found, virtually all new users of tobacco products are under the minimum legal age to purchase such products.<sup>15</sup>

Among the measures in the legislation to discourage tobacco use are provisions:

- Restricting cigarette marketing and sales to minors
- Granting FDA authority to further restrict tobacco product marketing
- Requiring detailed disclosure of cigarette and smokeless tobacco ingredients, including nicotine, and harmful smoke constituents
- Authorizing FDA to require changes to tobacco products in order to protect public health

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<sup>13</sup> FSPTCA, Public Law 111-31, Sec. 2. 21 U.S.C. 387.

<sup>14</sup> FSPTCA, Public Law 111-31, June 22, 2009 at Sec. 2, Finding 6 [21 U.S.C. 387 note].

<sup>15</sup> FSPTCA, Public Law 111-31, June 22, 2009 at Sec. 2, Finding 4 [21 U.S.C. 387 note].

- Regulating “modified risk” claims about tobacco products to prevent inaccurate and misleading claims
- Requiring bigger, bolder health warnings on cigarette and smokeless tobacco packages
- Requiring pre-market review of all new types of cigarettes or smokeless tobacco products
- Granting FDA authority to regulate the manufacturing facilities of tobacco products
- Requiring manufacturers and importers to submit comprehensive data on their cigarette and smokeless tobacco product testing and research to the FDA.

It is important to note that while the FSPTCA includes specific limitations on marketing, sales, and the content of tobacco products (including the characterizing flavor prohibition), it is clear that Congress intended that these measures constitute a foundation for additional action. The statute gives FDA broad authority to take additional steps to protect the public health from tobacco.

C. The prohibition of characterizing flavors in cigarettes is integrally related to the prevention of smoking initiation by young people

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The key regulatory provisions in the legislation direct the FDA to regulate tobacco products in order to “protect the public health.” Because all tobacco products cause death and disease, the legislation carefully defines protection of the public health to include not only measures designed to prevent cigarettes from becoming more toxic, but also measures designed to prevent tobacco products from being made particularly attractive to new users—and especially to youth, who, as noted above, constitute most potential new users. Thus, the provisions of the FSPTCA dealing with characterizing flavors are only one part of a comprehensive legislative effort to prevent cigarette marketing techniques that encourage young people to initiate tobacco use.

It has long been illegal in all States to sell cigarettes to underage users.<sup>16</sup> In spite of these prohibitions, however, cigarette manufacturers marketed and promoted cigarettes in order to encourage young people to smoke, and millions of young people have continued to initiate smoking despite previous legislative and regulatory efforts. Moreover, the tobacco companies designed cigarettes with the specific objective of making them more attractive to underage smokers.<sup>17</sup> The FSPTCA was intended to protect the public health by prohibiting tobacco companies from designing cigarettes to appeal to underage smokers. The prohibition on characterizing flavors was included in the legislation in order to help achieve this objective.

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<sup>16</sup> The large majority of states prohibit the sale of cigarettes to buyers under the age of 18. The minimum age is higher in a few states.

<sup>17</sup> *United States v. Philip Morris*, 449 F. Supp. 2d 1 (D.C.D.C. 2006).

Congress had before it evidence that the use of characterizing flavors effectively masks the harshness of tobacco smoke that would otherwise discourage many young people from smoking. Flavorings thus make cigarettes attractive to more new users. Prohibiting cigarettes characterized by candy, fruit or other exotic flavors that attract youth is designed to prevent manufacturers from making cigarettes particularly attractive to new users. The FSPTCA’s prohibition on characterizing flavors other than tobacco and menthol treats imported and domestically made cigarettes equally, and treats clove flavored cigarettes exactly as it treats all other cigarettes with the same flavorings. Clove cigarettes are attractive to youth, and thus fall into this category, but are only one of several similar flavorings prohibited by the Act.

### **III. Statutory Provisions Prohibiting the Use of Characterizing Flavors Were Included in Response to Efforts to Market Flavored Cigarettes to Youth**

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The prohibition of characterizing flavors in cigarettes was first included in the precursor legislation introduced in the 108<sup>th</sup> Congress in May of 2004 (H.R. 4433; S. 2461), with the exact same language that was ultimately passed into law in 2009. The language was initially included in the 2004 legislation at the behest of several senators who had become aware that flavored cigarettes were being marketed to attract underage users. Their objective was to prevent manufacturers from using characterizing flavors to attract new users who, in the absence of such flavorings, would have been less likely to initiate smoking.

During the 1990s, many state governments in the United States had sued the major tobacco companies, alleging that the death and disease caused by cigarettes had imposed massive health care costs on the States. The lawsuits also alleged that the companies had deliberately marketed cigarettes to underage users in order to ensure a continuing supply of customers. These lawsuits were settled by an agreement known as the Master Settlement Agreement of 1998 (“MSA”) between 46 States and the major tobacco companies under which the companies agreed to a number of marketing and promotion restrictions. Among these provisions was a prohibition on “targeting youth” in the advertising, marketing, and promotion of cigarettes.<sup>18</sup>

However, the MSA did not solve the problem of tobacco industry marketing to youth. Some companies were not covered by the MSA. In addition, faced with the restrictions imposed by the MSA, tobacco companies that had agreed to the MSA resorted to new marketing devices that appealed to youth. In 2003, Kretek began marketing a wide range of cigarettes with flavorings, such as strawberry, including a youth focused brand with the name *Liquid Zoo*. Beginning in 2004, R.J. Reynolds Tobacco Company

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<sup>18</sup> Master Settlement Agreement, Section III(a).



(“RJR”), the second largest domestic tobacco manufacturer in the United States, began to market cigarettes in many youth-friendly flavors such as vanilla, berry blend, peach, banana and strawberry. Moreover, these flavors were introduced using the Camel brand name, one of the brands most popular with underage smokers. “Camel Exotic Blends” came in flavors such as Twista Lime, Kauai Kolada, Warm Winter Toffee and Winter Mocha Mint, among others. Bright, colorful and alluring ads for these cigarettes appeared in magazines popular with youth, including *Rolling Stone*, *Cosmopolitan* and *Sports Illustrated*. RJR also marketed alcohol-flavored Camels with names like ScrewDriver Slots, Blackjack Gin and SnakeEyes Scotch. An article in *Convenience Store News* documented this trend - “flavored tobacco is offering a bright spot” - referring to the increased tobacco sales – and number of consumers – in stores that sell such products.<sup>19</sup> Although tobacco companies claimed to be responding to adult tobacco users’ demand for variety, these products primarily serve to lure new users, particularly youth, to a lifetime of addiction.

In response to RJR’s marketing campaign, a number of State attorneys general alleged that RJR’s marketing of such flavored cigarettes violated this provision, and they threatened to sue RJR to prevent such promotional activities. In 2006, the attorneys general and RJR reached an agreement under which RJR agreed to discontinue the sale of several flavored brands.<sup>20</sup> In addition, RJR agreed not to use specific terms such as “sweet” and “creamy” to market any future flavored cigarettes in media accessible to the general public.<sup>21</sup> However, for some time, the company continued to use these terms on its age-restricted website and in direct mail to consumers. Despite the agreement with the attorneys general, RJR subsequently released Camel Signature Blends in mid-2007, describing these cigarettes using words such as “sweet apple-like flavor,” “toasted honey,” and “creamy finish”. Thus, in spite of the agreement, RJR continued to sell flavored cigarettes and to advertise and promote them. Although the provisions of the MSA provided restrictions on the advertising and promotion of flavored cigarettes, they did not provide a basis for prohibiting the sale of flavored cigarettes.

Moreover, the agreement between the States and RJR applied only to that company. Other companies that were signatories to the MSA continued to market flavored cigarettes with appeal to young people, including Sweet Dream Cigarettes, in flavors like vanilla and chocolate mocha.<sup>22</sup> Furthermore, numerous tobacco manufacturers selling in the United States were not parties to the MSA and hence were not

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<sup>19</sup> “Flavors Add New Dimension to Tobacco,” *Convenience Store News*, October 1, 2007. RJR was only the most prominent of several companies that began to market flavored cigarettes aggressively during this period. For example, one company offered an array of flavored cigarettes with such youth-oriented names as “Liquid Zoo.”

<sup>20</sup> Attorneys General and R.J. Reynolds Tobacco Company Agreement October 11, 2006  
<http://www.law.state.ak.us/pdf/press/101106-flavored-settlement.pdf>.

<sup>21</sup> Although RJR entered a new settlement agreement agreeing to limit its marketing practices, no other tobacco companies were similarly bound by that agreement.<sup>29</sup>

<sup>22</sup> Sweet Dream Cigarettes and Camel Signature Blends were taken off the market in 2009.

subject to its provisions and continued to sell flavored cigarettes. As of January 2009, just prior to the enactment of the FSPTCA, at least 75 flavored brands and sub-brands that would be prohibited by the Act were being legally sold in New York.<sup>23</sup>

Members of Congress recognized the emergence of these new flavored cigarettes as a serious public health problem because of their particular appeal to young people. Candy-flavored cigarettes have their greatest appeal to new smokers, 90 percent of whom are teens or younger.<sup>24</sup> Established smokers are unlikely to give up their favorite brands for these new cigarettes, but young people will be tempted to try them and many will become addicted.<sup>25</sup>

Moreover, as noted above, there was evidence from scientific studies showing that flavorings are used in tobacco products to mask the harshness of the taste, and make the smoke taste better or milder and easier to inhale, and to attract youth.<sup>26</sup> For example, one study found that “[t]he use of sugars, honey, liquorice (sic), cocoa, chocolate and other flavorings make cigarettes more palatable and ‘aspirational’ – particularly to children and the young.”<sup>27</sup>

Tobacco companies had long recognized that flavorings could be used to facilitate and increase youth initiation. For example, a summary of a meeting held at RJR in 1974 discussed cigarettes designed for

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<sup>23</sup> The January, 20, 2009 New York State Office of Fire Prevention Control's "Cigarettes Certified by Manufacturers" list of brands and sub-brands allowed to be sold in the state pursuant to its fire safety laws still included more than 75 brands and sub-brands that are now prohibited by the FSPTCA prohibition on cigarettes with characterizing flavors other than menthol or tobacco. [Current list of Cigarettes Certified by Manufacturers available online at <http://www.dos.state.ny.us/fire/cigarette.htm>.]

<sup>24</sup> American Legacy Foundation, *First Look Report 17: Cigarette Preferences Among Youth--Results from the 2006 Legacy Media Tracking Online*, June 5, 2007, [http://americanlegacy.org/PDFPublications/fl\\_17.pdf](http://americanlegacy.org/PDFPublications/fl_17.pdf); Klein, SM, Giovino, GA, et al., "Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004-2005," *Nicotine & Tobacco Research* 10(7), July, 2008; SAMHSA, HHS, Calculated based on data in 2009 National Household Survey on Drug Use and Health, <http://www.oas.samhsa.gov/nsduh.htm>.

<sup>25</sup> HHS, *Youth and Tobacco: Preventing Tobacco Use among Young People: A Report of the Surgeon General*, 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); See also, Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, *Results from the 2010 National Survey on Drug Use and Health, NSDUH: Summary of National Findings*, 2011. <http://oas.samhsa.gov/NSDUH/2k10NSDUH/tabs/Sect4peTabs10to11.pdf>

<sup>26</sup> See, e.g., World Health Organization (WHO), *The Scientific Basis of Tobacco Product Regulation: Report of a WHO Study Group*, WHO Technical Report Series 945, 2007, [http://www.who.int/tobacco/global\\_interaction/tobreg/who\\_tsr.pdf](http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf). Carpenter CM, et al, "New Cigarette Brands with Flavors That Appeal to Youth: Tobacco Marketing Strategies," *Health Affairs* 24(6):1601-10, Nov-Dec, 2005, <http://content.healthaffairs.org/cgi/content/abstract/24/6/1601>. Carter SM, Chapman S, "Smokers and Non-smokers Talk About Regulatory Options in Tobacco Control," *15 Tobacco Control* 398, 2006.

<sup>27</sup> Bates, C, Jarvis, M, & Connolly, G, "Tobacco additives: Cigarette engineering and nicotine addiction," *ASH UK*, July 14, 1999, [http://www.sourcewatch.org/index.php?title=Tobacco\\_additives:\\_Cigarette\\_engineering\\_and\\_nicotine\\_addiction](http://www.sourcewatch.org/index.php?title=Tobacco_additives:_Cigarette_engineering_and_nicotine_addiction) See also, Wayne GF, Conolly GN, "How cigarette design can affect youth initiation into smoking: Camel cigarettes 1983-93," *Tobacco Control*, 11 (Suppl 1), 2002. Cummings KM, et al, "Marketing to America's youth: evidence from corporate documents," *Tobacco Control*, 11 (Suppl 1), 2002.

beginning smokers, noting that such a cigarette should be “low in irritation and possibly contain added flavors to make it easier for those who never smoked before to acquire the taste of it more quickly.”<sup>28</sup> Advisors to Brown & Williamson, a U.S. tobacco producer, also reviewed new concepts for a “youth cigarette,” including cola and apple flavors, and a “sweet flavor cigarette,” stating, “It’s a well-known fact that teenagers like sweet products. Honey might be considered.”<sup>29</sup> Other internal documents describe Tutti Frutti flavored cigarettes as “for younger people, beginner cigarette smokers, teenagers . . . when you feel like a light smoke, want to be reminded of bubblegum.”<sup>30</sup> There is also considerable evidence that the cigarette companies were using flavorings in cigarettes to market the cigarettes to specific populations, including marketing to minorities and youth.<sup>31</sup>

Young people are also more vulnerable to the marketing of flavored cigarettes.<sup>32</sup> For example, a June 2007 study by the American Legacy Foundation found that more than half of youth smokers (aged 13 to 18) who had heard of flavored cigarettes were interested in trying them, with 40 percent recalling seeing ads about them.<sup>33</sup> Another study found that college students, including nonsmokers, had higher positive expectancies and lower negative expectancies regarding flavored versions of cigarette brands compared to

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<sup>28</sup> R.J. Reynolds Tobacco Company, “Conference report #23,” June 5, 1974, Bates No. 500254578-4580.

<sup>29</sup> Marketing Innovations, “Youth Cigarette - New Concepts,” Memo to Brown & Williamson, September 1972, Bates No. 170042014.

<sup>30</sup> Report from R.M. Manko Assoc. to Lorillard Tobacco Co. (Aug. 1978), Bates No. 85093450-3480. See also, Dachille, K., *Pick Your Poison: Responses to the Marketing and Sale of Flavored Tobacco Products*, Tobacco Control Legal Consortium, February 2009.

<sup>31</sup> See, e.g., American Lung Association, Tobacco Policy Trend Alert, *From Joe Camel to Kauai Kolada – the Marketing of Candy-Flavored Cigarettes*, July 2005 [updated May 2006], American Lung Association, Tobacco Policy Trend Alert Addendum, *Alcohol-Flavored Cigarettes – Continuing the Flavored Cigarette Trend*, May 2006. Lewis MJ, Wackowski O, “Dealing with an Innovative Industry: A Look at Flavored Cigarettes Promoted by Mainstream Brands,” *American Journal of Public Health* 96:244-251, February, 2006, <http://www.ajph.org/cgi/content/abstract/96/2/244>. Carpenter CM, et al, “New Cigarette Brands with Flavors That Appeal to Youth: Tobacco Marketing Strategies,” *Health Affairs* 24(6):1601-10, Nov-Dec, 2005, <http://content.healthaffairs.org/cgi/content/abstract/24/6/1601>. Dachille, K., *Pick Your Poison: Responses to the Marketing and Sale of Flavored Tobacco Products*, Tobacco Control Legal Consortium, February 2009. National Cancer Institute, *NCI Cancer Bulletin Spotlight*, “Young Adults and Flavored Cigarettes: A Bad Combination,” March 14, 2006. See, also, Crawford, GE, “Flavored tobacco products with marijuana names,” *Tobacco Control* 16:70, February 2007, <http://tobaccocontrol.bmj.com/content/16/1/70.1.full.pdf>.

<sup>32</sup> See, e.g. Manning, KC et al., “Flavoured cigarettes, sensation seeking and adolescents’ perceptions of cigarette brands,” *Tobacco Control* 18(6): 459-65, December 2009, <http://tobaccocontrol.bmj.com/content/18/6/459.abstract?ct=ct>.

<sup>33</sup> American Legacy Foundation, *First Look Report 17: Cigarette Preferences Among Youth--Results from the 2006 Legacy Media Tracking Online*, June 5, 2007 [also finding that 11% had already tried flavored cigarettes], [http://americanlegacy.org/PDFPublications/fl\\_17.pdf](http://americanlegacy.org/PDFPublications/fl_17.pdf).

non-flavored versions.<sup>34</sup> A March 2008 poll showed that while one in every five youth (aged 12 to 17) had seen flavored tobacco products or ads, only one in ten adults had seen them.<sup>35</sup>

Given this evidence, it was reasonable for the U.S. Congress to conclude that teen smokers are much more likely to experiment with flavored cigarettes than young adult and adult smokers. According to a study by the Roswell Park Cancer Institute, approximately twenty-three percent of 17 year old smokers and twenty-two percent of 18-19 year old smokers had tried flavored cigarettes in the past 30 days, compared to less than ten percent of smokers aged 22 to 26, six percent of smokers aged 40-54, and less than one percent of smokers 55 years or older.<sup>36</sup> These research findings and industry document disclosures show that the FSPTCA prohibition on cigarettes with characterizing flavors other than tobacco or menthol was directed at preventing youth smoking initiation and reducing overall use, not only by eliminating the legal availability of such flavored cigarettes but by stopping related marketing efforts.<sup>37</sup> In fact, after reviewing the available research and evidence, the World Health Organization's Study Group on Tobacco Product Regulation recommended in 2007 that "regulations should be developed to prohibit manufacturing and marketing of candy-like and exotically flavored tobacco products targeting young and novice smokers." The Study Group also examined the evidence related to menthol and concluded that several scientific questions regarding menthol remained and did not recommend a prohibition on menthol.<sup>38</sup>

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<sup>34</sup> Ashare RL et al., "Smoking Expectancies for Flavored and Non-flavored Cigarettes Among College Students," *Addictive Behaviors* 32(6): 1252-61, June, 2007, <http://www.ncbi.nlm.nih.gov/pubmed/17030447>.

<sup>35</sup> National telephone survey of teens aged 12 to 17 and adults conducted by International Communications Research (ICR), March 2008.

<sup>36</sup> Klein, SM, Giovino, GA, et al., "Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004-2005," *Nicotine & Tobacco Research* 10(7), July, 2008.

<sup>37</sup> [Office of the New York Attorney General, press release, "Attorneys General and R.J. Reynolds Reach Historic Settlement to End the Sale of Flavored Cigarettes," October 11, 2006, [http://www.ag.ny.gov/media\\_center/2006/oct/oct11a\\_06.html](http://www.ag.ny.gov/media_center/2006/oct/oct11a_06.html). See, also, [http://www.ag.ny.gov/media\\_center/2006/oct/flavored%20settlement.final.pdf](http://www.ag.ny.gov/media_center/2006/oct/flavored%20settlement.final.pdf), and [http://www.ag.ny.gov/media\\_center/2006/oct/flavored%20settlement%20Appendix%20A%20final.pdf](http://www.ag.ny.gov/media_center/2006/oct/flavored%20settlement%20Appendix%20A%20final.pdf).] Despite the MSA settlement agreement with RJR regarding certain flavored cigarettes, the FSPTCA was still necessary to establish a more comprehensive prohibition that would apply to all cigarette manufacturers and importers, both to address the remaining problem with flavored cigarettes and to prevent the problem from ever getting worse.

<sup>38</sup> World Health Organization (WHO), *The Scientific Basis of Tobacco Product Regulation: Report of a WHO Study Group*, WHO Technical Report Series 945, 2007, Section 2.8 at 6 (see, also, Chapter 3), [http://www.who.int/tobacco/global\\_interaction/tobreg/who\\_tsr.pdf](http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf). That report did not, however, call for immediately prohibiting menthol cigarettes.

#### **IV. No Justification Exists for Excluding Clove-Flavored Cigarettes from the Prohibition**

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A. Clove cigarettes have all the characteristics of other flavored cigarettes that are covered by the prohibition and thus are “like products”

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Clove flavored cigarettes are indistinguishable from the other flavored cigarettes prohibited under the law. Clove cigarettes are similar to other candy and fruit flavored cigarettes in terms of their use of flavorings, appeal to children, market share, and frequency of use. There is nothing in the language of the FSPTCA provision that treats clove-flavored cigarettes differently from every other cigarette with a characterizing flavor other than tobacco or menthol without regard to their country of origin, and there is nothing to indicate that the treatment of clove cigarettes had anything to do with their country of origin. The language mentions "clove" as one of **thirteen flavors** listed as examples of the characterizing flavors other than tobacco or menthol equally prohibited in all cigarettes. The provision to prohibit cloves as a characterizing flavor is consistent with the overall intent of the law which is to reduce the number of children and adolescents who smoke cigarettes.<sup>39</sup> Therefore, the proper comparison in this instance is clove cigarettes against the broad array of “sweet-flavored” cigarettes covered by the statute because that is the actual category contained in the provision challenged and reflects both the clear intent and impact of the law. When the comparison is clove cigarettes versus all of the “sweet flavored” cigarettes prohibited by Section 907(a)(1)(A), it is clear that the statute impacts domestic cigarettes to an even greater degree than imported cigarettes. The WTO Panel both makes the wrong comparison and mischaracterizes incremental regulation as discrimination.

Just like other fruit and candy-flavored cigarettes, clove-flavored cigarettes often contain fruit and other sweet flavorings, which mask the harshness of the products and make them more appealing to children.<sup>40</sup> According to a leading manufacturer of kreteks (the most common type of clove-flavored cigarette), in addition to tobacco and cloves, “the final ingredient in any kretek is the sauce, a closely guarded recipe containing spice, fruit and herb extracts, and flavouring.”<sup>41</sup> As a major importer of a leading brand of clove cigarettes notes, not only is there the special sauce in clove cigarettes but “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 any regular cigarettes, and well-appreciated by kretek connoisseurs.”<sup>42</sup>

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<sup>39</sup> FSPTCA, Public Law 111-31, June 22, 2009 at Sec. 2, Findings 1-6, and 12, 14. 13 [21 U.S.C. 387 note].

<sup>40</sup> National Institute on Drug Abuse (NIDA), HHS, “Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes” *NIDA Notes* 18(2), August, 2003, accessed July 28, 2010.

<sup>41</sup> DJARUM, “Derived from Nature,” <http://www.djarum.com/index.php/en/history> accessed January 10, 2012.

<sup>42</sup> Demirtas, “Djarum Cigarettes & Cigars,” <http://www.demirtas.com.tr/Djarum.htm>, accessed July 27, 2010.

When Congress passed the FSPTCA in 2009, it was already clear that the availability of clove-flavored cigarettes contributed to increased smoking by youth. Survey data establishes that, similar to other flavored (non-menthol) tobacco products, clove flavored cigarettes are used disproportionately by younger smokers. Besides the already cited general research and industry documents on how candy, fruit and exotic flavors were used in cigarettes to increase youth initiation and overall use, the 2003 National Survey on Drug Use and Health (NSDUH) specifically showed that young people (12-17 year olds) were twice as likely as adults (age 26 or older) to have smoked clove cigarettes in the past month.<sup>43</sup> Also, according to the National Institute on Drug Abuse, clove cigarettes, “usually are sold in brightly colored packages and are sometimes referred to as ‘trainer cigarettes’ and may serve as ‘gateway’ products that introduce young people to smoking.”<sup>44</sup> The American Academy of Pediatrics Committee on Substance Abuse noted that “clove cigarettes should be suspected as a gateway drug because of their properties and the manner in which they are smoked.”<sup>45</sup>

In addition, the marketing of clove flavored cigarettes, like other flavored cigarettes, often emphasizes the unique and desirable experience that comes from the characterizing flavor. In fact, a leading kretek manufacturer positions its product as something different, saying that, “Enjoying a kretek means indulging in a completely different smoking experience; it means trying something new . . .”<sup>46</sup> Although kretek is an everyday smoke in Indonesia, “for international smokers in particular, kretek is likely to be a select indulgence, one reserved for special occasions.”<sup>47</sup> While those flavor characteristics of the typical clove cigarette attract youth and increase overall smoking levels, there is also research evidence that clove cigarettes deliver more tar and toxins to smokers than conventional cigarettes.<sup>48</sup>

The evidence summarized above supports Congress’s decision to include a prohibition on clove-flavored cigarettes in the section of the FSPTCA prohibiting cigarettes with characterizing flavors other than menthol and tobacco. Indeed, there was no valid public health reason for excluding them. Including clove-flavored cigarettes in the characterizing flavors prohibition makes the prohibition a more effective tool to

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<sup>43</sup> HHS, Substance Abuse and Mental Health Services Administration (SAMHSA), Results from the 2003 National Survey on Drug Use and Health, September, 2004.

<sup>44</sup> National Institute on Drug Abuse (NIDA), HHS, “Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes” *NIDA Notes* 18(2), August, 2003, accessed July 28, 2010.

<sup>45</sup> American Academy of Pediatrics, Committee on Substance Abuse, “*Hazards of Clove Cigarettes*,” *Pediatrics* 88(2), August 1991. <http://pediatrics.aappublications.org/cgi/content/abstract/88/2/395>

<sup>46</sup> DJARUM, “Enjoying Kretek Cigarettee,” <http://www.djarum.com/index.php/en/history> accessed January 10, 2012.

<sup>47</sup> DJARUM, “Kretek Today,” <http://www.djarum.com/index.php/en/history> accessed January 10, 2012.

<sup>48</sup> National Institute on Drug Abuse (NIDA), HHS, “Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes” *NIDA Notes* 18(2), August, 2003, accessed July 28, 2010., Nadel, J. et al., Letter, “Disparities in Global Tobacco Harm Reduction,” *American Journal of Public Health* 95(12): 2120, December 2005, <http://www.ajph.org/cgi/reprint/95/12/2120>.

prevent smoking initiation and reduce overall use. In addition, because of the relatively small number of smokers of clove-flavored cigarettes, as well as the fact of only occasional use of clove cigarettes by smokers, it was exceptionally unlikely that there would be any serious unintended public health consequences from the prohibition. There were no indications that including clove-flavored cigarettes in the FSPTCA prohibition (or implementing the FSPTCA prohibition as a whole) created any risk of any significant public health harms that could possibly offset the likely public health benefits. Indeed, the prohibition on clove and other non-menthol flavored cigarettes has been in place since September 20, 2009, and no such problems have been documented.

B. The provisions of the statute apply equally to domestic and imported cigarettes and do not accord less favorable treatment to cigarettes manufactured outside the United States

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The law's prohibition on flavored cigarettes applies to any and all cigarettes with characterizing flavors other than menthol without distinction as to whether they are imported or produced domestically. Moreover, the provisions of the law dealing with the adoption of a regulatory standard for menthol cigarettes also apply equally to domestic and foreign manufactured cigarettes. Thus, the statute does not accord less favorable treatment to cigarettes manufactured outside the United States. Moreover, if and when FDA acts to restrict or prohibit the sale of cigarettes with a menthol characterizing flavor, such regulatory action will apply equally to domestic and foreign manufactured cigarettes.

**V. In Evaluating How the U.S. Tackled the Challenging Problem of Curtailing the Availability of Different Tobacco Products that Unduly Appeal to Youth, the WTO Panel Failed to Give the U.S. Adequate Discretion in Determining How Best to Protect the Public Health of its Citizens Given the Legitimacy of the U.S.'s Public Health Concerns, the Presence of Different Factual Circumstances Surrounding the Different Products, and the Absence of Any Intent to Discriminate**

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The issue presented by this case is not whether the WTO would have made the same difficult judgments made by the United States. Rather, the issue is whether under the circumstances the United States should be given the discretion to address a complex problem of extraordinary public health consequence, where the WTO has concluded that the prohibition on clove cigarettes addresses a legitimate public health issue and concluded that Indonesia has failed to demonstrate that the clove cigarettes' prohibition imposed by Section 907(a)(1)(A) is more trade-restrictive than necessary to fulfill the legitimate objective of reducing youth smoking. Countries must be given the discretion to adopt public health policies to address the tobacco problem incrementally and to make assessments of their unique own national circumstances in determining how to do so based upon the scientific evidence then available.

In many respects cigarettes pose unique challenges to governments. There is a worldwide consensus that cigarettes are both deadly and addictive, but cigarette smoking became widespread before there was a general recognition of its adverse health effects. For many years cigarettes were sold without any effective regulation because the health effects of their use were not recognized. There is little question, however, that the sale of cigarettes would not have been permitted at all had there been a recognition of their health effects at the time when they were first marketed or before they had achieved significant acceptance in the market. The fact that these products have been sold for decades and that millions of people in the U.S. and around the world are addicted to these deadly products means that the global effort to reduce their use inevitably depends upon incremental steps based upon often difficult judgments about how to best reduce the use of a product with millions of already addicted consumers.

In this instance, the U.S. was faced with a host of newly introduced flavored products used mostly by youth and not yet used by a large number of long term users or heavily addicted users. Congress prohibited the flavored products based on clear evidence a) that these products appealed primarily to children; and b) that their immediate prohibition would not create withdrawal problems for consumers or difficult law enforcement problems. In other words, the U.S. Congress did what it believed would have a virtually guaranteed positive public health effect by banning flavored products. At the same time, Congress gave the FDA, an agency with the necessary scientific expertise, authority to evaluate the exact effect of menthol cigarettes on youth tobacco use. In addition, to best promote public health, Congress gave the FDA authority to devise the best strategy for expeditiously addressing the problem of menthol cigarettes, in light of the reality of millions of adult consumers who were already addicted to menthol products.

As we have already noted, the evidence is strong that all of the flavored cigarettes prohibited by the FSPTCA appeal to youth and could safely be taken off the market without creating unforeseen problems because of their small market share and the fact that there was no evidence that consumers had yet become heavily addicted to these products. In contrast, menthol cigarettes have been in use in the U.S. for decades and constitute approximately 27% of the overall U.S. market.<sup>49</sup> More than 12 million Americans, including more adults than youth, regularly smoke menthol cigarettes.<sup>50</sup> Given the prevalence of menthol cigarettes and the fact that millions of Americans were addicted to them, adoption of an appropriate regulatory policy represented a far more difficult problem.

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<sup>49</sup> U.S. Federal Trade Commission (FTC), "Cigarette Report for 2004 and 2005," Table 7 (2007), <http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf>. Also based on data in 2006 National Health Interview Survey.

<sup>50</sup> U.S. Federal Trade Commission (FTC), "Cigarette Report for 2004 and 2005," Table 7 (2007), <http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf>. Also based on data in 2006 National Health Interview Survey.



In making the determination that the best and safest public policy was to have the FDA study the role of menthol cigarettes and how best to deal with the public health problems posed by menthol cigarettes, the U.S. Congress was acting well within its discretion and making a public health judgment that it should be entitled to make given the facts. When Congress first drafted Section 907(a)(1)(A) the United States National Cancer Institute had recently conducted a scientific Consensus Conference that had studied menthol cigarettes. The National Cancer Institute issued a report of that Conference which concluded that the role of menthol was still uncertain and recommended the need for additional research. It did not recommend that menthol cigarettes be immediately prohibited.<sup>51</sup>

In addition, while Congress could be confident that a prohibition on the newly introduced and not yet widely used flavored cigarettes would not cause addiction withdrawal issues for millions of consumers or run any risk of generating a black market, it was not unreasonable for Congress to determine for menthol cigarettes that those issues needed to be studied before action was taken with regard to those products. Nor was it unreasonable for Congress to give the authority to a regulatory agency with broad powers to develop how best to reduce the harm caused by menthol cigarettes. The statute directed a panel of distinguished scientific experts, the Tobacco Products Scientific Advisory Committee, to undertake a study of the effects of menthol cigarettes on public health and to submit its recommendations to the FDA.<sup>52</sup>

The WTO Panel mischaracterizes the rationale for the U.S.'s treatment of menthol cigarettes. Contrary to the inaccurate characterization of the Panel, the U.S. decision was not based on its concern about the "costs" of such a prohibition,<sup>53</sup> but was based on the same consistent public health concerns that guided its decision making throughout the statute. The articulated goal was reducing youth tobacco use and doing so in a way that would have the greatest public health impact and raise the fewest public health problems. It was not beyond its lawful discretion for Congress to conclude that it did not have before it sufficient evidence to make those judgments with regard to menthol cigarettes; it had sufficient evidence to make those judgments with regard to the many products that were immediately prohibited.

Congress did not ignore or exempt menthol cigarettes. The statute gives the FDA authority to prohibit the sale of menthol cigarettes. It directs the FDA to study and consider 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.<sup>54</sup> The FDA is authorized to set a product standard

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<sup>51</sup> US Department of Health and Human Services, National Institutes of Health, *The First Conference on Menthol Cigarettes: Setting the Research Agenda*, Executive Summary, 2002.

<sup>52</sup> FSPTCA, Pub.L. 111-31, sec. 907(e).

<sup>53</sup> Panel Report, *US Clove Cigarettes*, para.7.293.

<sup>54</sup> FSPTCA, sec. 907(e).

applicable to menthol cigarettes that could restrict or prohibit the sale of such cigarettes.<sup>55</sup> In establishing the product standard, the FDA is directed to consider the effect of such a standard on the public health, including the effect on initiation of tobacco use by non-users and the effect on quitting by existing users as well as information concerning potential countervailing effects of the standard on the health of adolescent users, adult users, and non-tobacco users, such as the creation of a possible demand for contraband products.<sup>56</sup>

The statutory process also enables the FDA to develop consumer education programs and increased resources for support mechanisms to help menthol smokers quit if menthol cigarettes were prohibited. Congress was acting well within its legitimate discretion in determining that menthol cigarettes posed different issues that required a more sophisticated evaluation and approach to insure that the statute's public health goals would be achieved. Neither the *Technical Barriers to Trade Agreement* nor any other trade agreement should be interpreted to deprive a country of the ability to fashion its public health laws in ways that address legitimate concerns and facts unique to their own circumstances.

The prohibition on the sale of non-menthol flavored cigarettes was an important and appropriate regulatory response to a very real public health problem. The adoption of a more measured response to menthol cigarettes, which entailed a more complex set of issues, should not be used to undercut such an important public health initiative. Governments must be able to adopt measures to deal with severe threats to the public health by making reasonable judgments that treat different categories of products in different ways. In this case, it would be inappropriate to rule that in developing a policy to deal with flavored cigarettes, a government could not legitimately distinguish between two classes of flavored cigarettes that Congress in good faith for legitimate public health reasons determined present different sets of regulatory problems. Such a ruling would make it more difficult for governments to take effective measures to protect the public health of their citizens.

## **VI. The Panel Mischaracterizes as Discriminatory the U.S.'s Incremental Steps to Address a Long Term Public Health Problem**

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Tobacco products, unlike any other consumer product, are harmful and deadly even when used precisely as intended. Unlike other legal products, tobacco products are also highly addictive, with the vast majority of all users beginning to consume tobacco products before reaching the minimum legal age – and with most addicted adult consumers wanting to quit but finding it very difficult to do so.

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<sup>55</sup> FSPTCA, sec. 907.

<sup>56</sup> FSPTCA, sec. 907(b).

Unfortunately, there is no magic bullet to prevent and reduce the massive amount of unnecessary harm and death caused by tobacco use. Given the unique and complex nature of the product, its marketing, and the ingenuity of the tobacco companies, reducing tobacco use will be an ongoing long-term effort that includes incremental steps of varying magnitude. As described above, the FSPTCA included specific limitations on the sale, marketing, and manufacture of tobacco products, but the entire approach of the statute recognizes that the specific limitations are part of an evolving process. The law gave the FDA the broad authority to continue to bring the best science to bear in adopting new approaches to reducing tobacco use. Enhanced scientific knowledge will become the basis for additional and more effective regulatory approaches. These approaches may include further marketing restrictions, product standards, prohibitions on additional tobacco products, new warning labels, and other measures to further reduce tobacco use and respond to the inevitable efforts by tobacco companies to continue to promote their deadly products.

The U.S. treatment of the many versions of flavored tobacco products, including strawberry, vanilla, clove and menthol is consistent with this approach. Where Congress concluded it had adequate evidence about the nature of the problem and the effectiveness of the regulatory response, it ordered a prompt prohibition; where it believed that FDA would be in a better position to evaluate the evidence or address problems Congress had not identified, it gave the authority to FDA to identify, develop and implement the most effective and appropriate regulatory response.

It would undermine legitimate public health policy to conclude that the legislation could prohibit some flavors only if it prohibited all flavors. Such a conclusion would prevent the development of effective regulatory policies and prevent the implementation of public health measures based on evolving scientific knowledge. Prohibiting flavored cigarettes, including clove-flavored cigarettes, was a regulatory action within the legitimate discretion of Congress. Although flavored cigarettes presented a serious and increasing public health problem, flavored cigarettes were still a new, emerging product and the number of users was not yet so large that removing such cigarettes from the market was likely to present significant unforeseen consequences. By contrast, potential removal of menthol cigarettes, to which 12 million Americans were already addicted, presented a more complex regulatory problem requiring the development of an appropriate regulatory policy by the FDA.

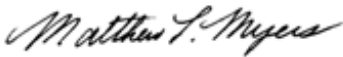
## **VII. Conclusion**

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Congress acted appropriately when it included clove among the prohibited cigarette flavorings. Prohibiting such flavorings was designed to reduce youth smoking, consistent with the overarching purpose

of the FSPTCA. Congress's decision to prohibit clove cigarettes must be understood in light of the overall purpose of the law – to reduce the toll of death and disease from tobacco use, and prevent youth smoking. The issues presented by menthol cigarettes in the United States market were more complex, and the adoption of different regulatory requirements presents no basis for concluding that such measures violate international trade agreements.

Respectfully submitted,



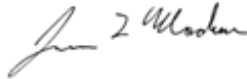
Matthew L. Myers  
President  
Campaign for Tobacco-Free Kids



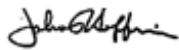
Charles D. Connor  
President and Chief Executive Officer  
American Lung Association



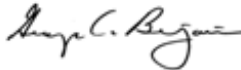
Robert W. Block, MD, FAAP  
President  
American Academy of Pediatrics



James L. Madara, MD  
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American Medical Association



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American Public Health Association