



September 15, 2010

Ambassador Ron Kirk  
United States Trade Representative  
600 17th Street, N.W.  
Washington, DC 20508

Re: WTO Dispute Settlement Proceeding Regarding United States—Measures Affecting the Production and Sale of Clove Cigarettes [Docket number: USTR-2010-0013]

Dear Ambassador Kirk:

Given the importance of protecting effective national tobacco control measures from challenges through the World Trade Organization (WTO), your office's steadfast opposition to Indonesia's disputing the ban on the sale of all cigarettes with characterizing flavors other than tobacco or menthol in the Family Smoking Prevention and Tobacco Control Act (FSPTCA) has been commendable, appropriate, and fully justified. We recognize that your office already has a good understanding of the relevant facts and issues, but we hope that this letter will provide some additional facts and insights to fortify the ongoing efforts of the United States to protect the FSPTCA.

We also send this letter to stress the critical importance of blocking and refuting the trade-based arguments of Indonesia on the FSPTCA for protecting and promoting public health, not just because of the public health benefits of the FSPTCA ban on flavored cigarettes, but because of the destructive precedent that might be set to threaten many other government public health laws if Indonesia's claims were successful.

As set forth in more detail and with references below, banning cigarettes with candy, fruit or other exotic flavors that attract youth is an effective way to help prevent smoking initiation and reduce overall tobacco use and harms. In its implementation of such a ban, the FSPTCA treats imported and domestically made cigarettes equally and treats clove flavored cigarettes exactly like all other flavored cigarettes other than those with a characterizing flavor of tobacco or menthol. Indeed, clove cigarettes are not significantly different from any of the other prohibited flavored cigarettes, being used by only a relatively small number of adult smokers, typically on an occasional basis, while also being especially attractive to youth and providing an entryway cigarette that masks the harshness of unflavored cigarettes.

Cigarettes with a characterizing flavor of menthol were excluded by Congress from the FSPTCA prohibition because menthol cigarettes – unlike all other cigarettes with any other characterizing flavor other than just tobacco – were currently being regularly used by a large number of addicted adult users, with the number of menthol smokers well in excess of the total number of adults regularly smoking all other cigarettes subject to the ban. Accordingly, Congress determined that the public health benefits and any possible public health consequences from banning menthol needed to be investigated and considered more carefully before any action might be taken to prohibit menthol-flavored cigarettes. Because of their relatively trivial use

rates, however, Congress determined that prohibiting any or all of the other characterizing flavors did not raise any similar concerns and could be done immediately to help prevent youth initiation and reduce tobacco use and its harms.

Accordingly, the decision by Congress to exclude menthol from the FSPTCA ban on all cigarettes with characterizing flavors other than tobacco was reasonable, based on clear differences between menthol-flavored cigarettes and their use compared to any other flavored cigarettes. No parallel reasons exist for also excluding clove or any other flavored cigarettes.

At the same time, in passing the FSPTCA, Congress did not in any way leave menthol cigarettes (or their manufacturers or importers) unregulated. Besides giving FDA clear authority to prohibit menthol cigarettes in the future if it determined that doing so would promote the public health, the FSPTCA also directed the FDA's Scientific Advisory Committee to consider the menthol issue and make a report with recommendations to FDA no later than one year after the Committee was established, which will be March 23, 2011. In the meantime, menthol cigarettes are subject to all of the many new marketing restrictions and other requirements established for all cigarettes by the FSPTCA, and the FSPTCA also requires FDA to publish an action plan to enforce restrictions on the marketing and promotion of "menthol and other cigarettes to youth" by October 1, 2010.

**The FSPTCA was enacted to protect the public health against death and disease caused by the use of tobacco products.**

The FSPTCA was enacted as a public health measure to deal with harms caused by smoking and other tobacco use. As the statutory findings in the Act state, tobacco use is the foremost preventable cause of premature death in America, causing over 400,000 deaths in the United States each year.<sup>1</sup> In addition, Congress found that past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, and that comprehensive restrictions on the sale, promotion, and distribution of such products are needed.<sup>2</sup> The operative provisions of the FSPTCA enact a wide range of restrictions on the advertising, promotion and marketing of cigarettes and smokeless tobacco products and give FDA broad regulatory authority over all tobacco products and their marketing.

The provisions of the FSPTCA dealing with characterizing flavors are only one aspect of a comprehensive statute giving the FDA broad regulatory authority over tobacco products. The legislation covers a large number of areas including:

- 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 to protect the public health
- Regulating “reduced harm” claims about cigarettes and smokeless tobacco to prevent inaccurate and misleading claims
- Requiring bigger, bolder health warnings on cigarette and smokeless tobacco packages

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

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

- Requiring pre-market review of all new types of cigarettes or smokeless tobacco products
- Grants 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 of and research to the FDA.

It is abundantly clear both from the statutory findings, the statement of statutory purpose, and the operative provisions of the statute that the legislation is directed at promotion of public health and protection of the public—and especially children—from the death and disease caused by tobacco products. Although the provisions regarding cigarettes with characterizing flavors are only one component of the legislation, they too have a clear purpose of protecting the public health.

**Banning Cigarettes with Characterizing Flavors Other than Tobacco or Menthol is an Effective Way to Help Prevent Smoking Initiation and Reduce Overall Tobacco Use.**

Preventing smoking initiation among youth is an essential objective of federal tobacco control policy.<sup>3</sup> As Congress pointed out prior to passing the FSPTCA, virtually all new users of tobacco products are under the minimum legal age to purchase such products.<sup>4</sup> The statutory ban on characterizing flavors is closely linked to the policy of preventing youth smoking.

Scientific studies show 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>5</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>6</sup>

Tobacco industry documents disclosed in various lawsuits or pursuant to related settlements also describe how tobacco companies use flavorings to facilitate and increase initiation and attract

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<sup>3</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].

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

<sup>5</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>6</sup> Bates, C, Jarvis, M, & Connolly, G, “Tobacco additives: Cigarette engineering and nicotine addiction,” ASH UK, July 14, 1999, [http://newash.org.uk/files/documents/ASH\\_623.pdf](http://newash.org.uk/files/documents/ASH_623.pdf). 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.

youth. For example, a 1974 summary of a meeting held at R.J. Reynolds discussed cigarettes designed for 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>7</sup> Advisors to Brown & Williamson 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>8</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>9</sup> There is also considerably evidence that the cigarette companies use flavorings in cigarettes to market the cigarettes, including marketing to minority and youth.<sup>10</sup>

Young people are also more vulnerable to the marketing of flavored cigarettes.<sup>11</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,

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<sup>7</sup> R.J. Reynolds Tobacco Company, “Conference report #23,” June 5, 1974, Bates No. 500254578-4580.

<sup>8</sup> Marketing Innovations, “Youth Cigarette - New Concepts,” Memo to Brown & Williamson, September 1972, Bates No. 170042014.

<sup>9</sup> Report from R.M. Manko Assoc. to Lorillard Tobacco Co. (Aug. 1978), Bates No. 85093450-3480. See also, Dachele, K., *Pick Your Poison: Responses to the Marketing and Sale of Flavored Tobacco Products*, Tobacco Control Legal Consortium, <http://tclconline.org/documents/flavored-tobacco.pdf>, February 2009.

<sup>10</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], <http://slati.lungusa.org/reports/CandyFlavoredUpdatedAlert.pdf>. 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>. 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>. Dachele, K., *Pick Your Poison: Responses to the Marketing and Sale of Flavored Tobacco Products*, Tobacco Control Legal Consortium, <http://tclconline.org/documents/flavored-tobacco.pdf>, February 2009. National Cancer Institute, *NCI Cancer Bulletin Spotlight*, “Young Adults and Flavored Cigarettes: A Bad Combination,” March 14, 2006, <http://www.cancer.gov/aboutnci/ncicancerbulletin/archive/2006/031406/page4>. 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>11</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>.

with 40 percent recalling seeing ads about them.<sup>12</sup> Another study found that college students, including nonsmokers susceptible to smoking initiation, had higher positive expectancies and lower negative expectancies regarding flavored versions of cigarette brands compared to non-flavored versions.<sup>13</sup>

Given the above, it is not surprising that scientific evidence also shows 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>14</sup>

More specifically, the 2003 *National Survey on Drug Use and Health (NSDUH)* found that youth (12-17 year olds) and young adults (18-25 year olds) were much more likely than older adults (age 26 or older) to have smoked clove cigarettes in the past month.<sup>15</sup>

These research findings and industry document disclosures show that the FSPTCA ban on cigarettes with characterizing flavors other than tobacco or menthol will work directly to prevent youth smoking initiation and reduce overall use, not only by eliminating the legal availability of such flavored cigarettes but by stopping related marketing efforts.<sup>16</sup> In fact, after reviewing the

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<sup>12</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).

<sup>13</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>14</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>15</sup> Substance Abuse and Mental Health Administration (SAMHSA), U.S. Department of Health and Human Services (HHS), *Results from the 2003 National Survey on Drug Use and Health*, Table 7.60B, September, 2004, <http://www.oas.samhsa.gov/nhsda/2k3nsduh/2k3Results.htm>. Unfortunately, the *NSDUH* reports have not included data on clove cigarette use in subsequent years.

<sup>16</sup> It is not relevant that the prevalence of such flavored cigarettes and related marketing had already been reduced prior to the passage of the FSPTCA because the Master Settlement Agreement (MSA) between 46 states and roughly forty U.S. manufacturers and foreign importers of cigarettes had already been used in 2006 to stop the R.J. Reynolds Tobacco Company from selling certain brands and sub-brands of cigarettes with candy, fruit and other characterizing flavors and prohibiting the future marketing or sale of any other such cigarettes in ways that reached or influenced youths (basically restricting their marketing and sale to adult-only venues or websites), with other manufacturers and importers of cigarettes subject to the MSA thereby put on notice that the MSA would be enforced against them if they did not follow the same restrictions, as well. [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,

available research and evidence, the World Health Organization's Study Group on Tobacco Product Regulation recommended in 2007 that "Regulation should be developed to prohibit manufacturing and marketing of candy-like and exotically flavored tobacco products targeting young and novice smokers."<sup>17</sup>

**Congress Implemented the FSPTCA Ban on Characterizing Flavors Solely to Protect the Public Health with No Intent to Discriminate Against Imports or to Favor Domestic Products.**

It is clear from the legislative history of the FSPTCA that its ban on cigarettes with characterizing flavors other than tobacco or menthol was designed to protect the public health and was not included in the Act with any intent to favor U.S. products or businesses, much less to discriminate against any imports or foreign businesses or countries. The FSPTCA is the product of many years of legislative efforts; and the characterizing flavor ban was first added into 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 the FSPTCA. The language was initially included in the legislation after some Senators had seen various new cigarette brands with kid-attracting flavors, and related advertising, and wanted to stop the

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[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).] While the attorneys general Agreement severely hindered R.J. Reynolds's ability to market youth-flavored cigarettes in ways that reach youth, it legally applied only to R.J. Reynolds and, even if extended to apply to all other cigarette manufacturers and importers subject to the MSA, would not and could not have reached the many non-participating manufacturers and importers. In addition, the agreement actually left R.J. Reynolds free to make and sell flavored cigarettes – because RJR has agreed only that it would not market or advertise *to the general public* any flavored cigarettes using scented promotional materials or fruit, candy or alcoholic beverage type words or images. Under the agreement, R.J. Reynolds could still use such scented promotional materials in adult-only venues and could use fruit, candy or alcohol words or images in marketing or advertising flavored cigarettes in adult-only facilities or via adult-only emails, mail or other communications, which could have substantial spillover effects that still reached youth. Despite the MSA settlement agreement with R.J. Reynolds 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. For example, 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 ban 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>17</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 banning menthol cigarettes.

flavored cigarettes brands from attracting significant numbers of youth into smoking before they gained significant market share.

Clove-flavored cigarettes were treated exactly like all other cigarettes with characterizing flavors other than tobacco or menthol; and menthol-flavored cigarettes were not automatically banned because they, alone, already controlled a substantial market share among adult smokers. At the same time, specific language was included to make it clear that FDA still retained clear authority to restrict or ban the sale of cigarettes with a characterizing menthol flavor if it determined that such action would promote the public health.<sup>18</sup>

We are not aware of any evidence that the provision was included in the FSPTCA, or ultimately passed into law by the Congress, for trade discrimination purposes, or for any reason other than to promote and protect public health. In particular, there is no evidence that the provision was supported or passed by the Congress in order to discriminate against imports of clove-flavored cigarettes.

**The FSPTCA Treats Clove-Flavored Cigarettes Just Like All Other Cigarettes with a Characterizing Flavor Other Than Tobacco or Menthol .**

There is nothing in the language of the FSPTCA provision that treats clove-flavored cigarettes differently than every other cigarette with a characterizing flavor other than tobacco or menthol. The language mentions "clove" only as one of thirteen flavors listed as examples of the characterizing flavors other than tobacco or menthol that the provision equally prohibits in all cigarettes.

**The FSPTCA Imposes Strong Regulatory Measures on The Sale of Menthol Cigarettes.**

Although Congress did not directly ban menthol cigarettes, it took steps to ensure that FDA would promptly consider the appropriateness of such a ban. The legislation makes it clear that FDA retains full authority to ban menthol cigarettes if it determines that doing so is appropriate to protect the public health.<sup>19</sup> Moreover, the FSPTCA specifically directs the FDA's Scientific Advisory Committee, within one year after it is first established, to issue a report, with recommendations, to FDA on "the impact of the use of menthol in cigarettes on the public health, including such use among African Americans, Hispanics, and other racial and ethnic

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<sup>18</sup> The language in the 2004 legislation, identical to the language in the FSPTCA, states that nothing in the provision banning cigarettes with characterizing flavors other than tobacco or menthol "shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol." That section, Tobacco Product Standards, provides FDA with authority to adopt new tobacco product standards if it "finds that a tobacco product standard is appropriate for the protection of the public health."

<sup>19</sup> FSPTCA, Public Law 111-31, June 22, 2009 at "Sec. 907(a)(1)(A) [21 U.S.C. 387g(a)(1)(A)].

minorities."<sup>20</sup> And the primary legislative report relating to the FSPTCA urges FDA to address the menthol cigarette issue "as quickly as practicable."<sup>21</sup>

That provision's reference to the Scientific Advisory Committee's report and recommendations addressing various factors required by the Tobacco Product Standards section of the Act indicates that Congress fully understood that the Advisory Committee might, based on available research and data, recommend a new tobacco product standard for menthol cigarettes (which could parallel the FSPTCA tobacco product standard prohibiting cigarettes with characterizing flavors other than tobacco). Moreover, the FSPTCA provision directly requires the Scientific Advisory Committee's report on menthol and related recommendations to address such matters as the risks and benefits to the population as a whole, including users and nonusers of tobacco products; the increased or decreased likelihood that existing users will stop using such products; and the countervailing effects of any proposed new product standard relating to menthol on the health of adolescent and adult tobacco users or nontobacco users, including the creation of a significant demand for contraband or other tobacco products. In other words, the report must address the concerns that prompted Congress to exclude menthol for the FSPTCA's ban on characterizing flavors, as described in the Congressional reports on the FSPTCA.<sup>22</sup>

Perhaps anticipating that possibility that unforeseen events might delay the formal release of the final Scientific Advisory Committee report and recommendations, Congress also makes it very clear in the FSPTCA that FDA need not wait for the Advisory Committee's final report and recommendations before it takes additional action on menthol cigarettes.<sup>23</sup> In particular, the FSPTCA requires FDA to publish an action plan to enforce restrictions on the marketing and promotion of menthol and other cigarettes to youth by October 1, 2010.<sup>24</sup>

Moreover, menthol cigarettes are already subject to all of the new marketing restrictions and other requirements that the FSPTCA applies to all cigarettes. For example, menthol cigarettes, themselves, cannot have any characterizing flavors other than tobacco and menthol (which has prohibited the sale of various brands and sub-brands), and the marketing and sale of menthol cigarettes must comply with all the new restrictions and requirements in the restored 1996 Final Rule, which went into effect on June 22, 2010.<sup>25</sup>

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<sup>20</sup> FSPTCA, Public Law 111-31, June 22, 2009 at "Sec. 907(e)" [21 U.S.C. 387g(e)].

<sup>21</sup> Committee on Energy and Commerce, U.S. House of Representatives, *Family Smoking Prevention and Tobacco Control Act*, Report No. 11-58, Part 1, March 26, 2009 at page 38.

<sup>22</sup> Committee on Energy and Commerce, U.S. House of Representatives, *Family Smoking Prevention and Tobacco Control Act*, Report No. 11-58, Part 1, March 26, 2009 and Committee on Energy and Commerce, U.S. House of Representatives, *The Family Smoking Prevention and Tobacco Control Act*, Report No. 11-762, July 17, 2008.

<sup>23</sup> FSPTCA, Public Law 111-31, June 22, 2009 at "Sec. 907(e)(3)" [21 U.S.C. 387g(e)(3)].

<sup>24</sup> FSPTCA, Public Law 111-31, June 22, 2009 at Sec. 105(a) [21 U.S.C. 387f-1(a)].

<sup>25</sup> Food and Drug Administration, HHS, "Final Rule, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents," 21 CFR 1140, *Federal Register* 75(53): 13225-13232, March 19, 2010.

These provisions in the FSPTCA ensure that the public health problems with the availability and marketing of menthol cigarettes are already being addressed to some extent and will be addressed more directly in the near future – with the federal government's new actions in regard to menthol cigarettes based on the strongest scientific base possible to protect the public health.

**No Justification Exists for Excluding Clove-Flavored Cigarettes from the Ban.**

When the FSPTCA was passed into law it was already clear that the availability of clove-flavored cigarettes does contribute to increased smoking by youth. 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 two times more likely than adults (age 26 or older) to have smoked clove cigarettes in the past month.<sup>26</sup> That is not surprising because clove cigarettes often contain fruit and other sweet flavorings, which mask the harshness of the products and make them more appealing to children.<sup>27</sup> In addition, 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>28</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>29</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>30</sup>

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<sup>26</sup> SAMHSA, HHS, Results from the 2003 National Survey on Drug Use and Health, September, 2004, <http://www.oas.samhsa.gov/nhsda/2k3nsduh/2k3Results.htm>.

<sup>27</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, [http://archives.drugabuse.gov/NIDA\\_notes/NNVol18N2/Alternative.html](http://archives.drugabuse.gov/NIDA_notes/NNVol18N2/Alternative.html).

<sup>28</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, [http://archives.drugabuse.gov/NIDA\\_notes/NNVol18N2/Alternative.html](http://archives.drugabuse.gov/NIDA_notes/NNVol18N2/Alternative.html).

<sup>29</sup> PT DJARUM, “A Product of Nature,” <http://www.djarum.co.id/en>, accessed March 24, 2009. See, also, <http://www.djarum.com/?mod=historyofkretek>.

<sup>30</sup> Demirtas, “Djarum Cigarettes & Cigars,” <http://www.demirtas.com.tr/Djarum.htm>, accessed July 27, 2010.

While those flavor characteristics of the typical clove cigarette certainly work to attract youth and increase overall smoking levels, there is also research evidence that clove cigarettes deliver more tars and toxins to smokers than conventional cigarettes.<sup>31</sup>

Given all of this information, there were plenty of valid public health reasons for including clove-flavored cigarettes in the FSPTCA's ban of cigarettes with characterizing flavors other than tobacco and no valid public health reasons for excluding them.

Including clove-flavored cigarettes in the ban clearly makes it more effective as a tool for helping to prevent smoking initiation and reduce overall use. On the other hand, because of the relatively small number of smokers of clove-flavored cigarettes and the typical only occasional use of clove cigarettes by smokers, there were no unresolved issues or questions about clove cigarettes or their use (or about any of the other banned flavored cigarettes or their use) that needed to be resolved prior to passing or implementing the FSPTCA characterizing flavor ban in order to ensure that there would not be any serious unintended public health consequences. There were no indications at all that including clove-flavored cigarettes in the FSPTCA ban (or implementing the FSPTCA ban as a whole) created any risk of any significant public health harms that could possibly offset the likely public health – and the ban on clove and other non-menthol flavored cigarettes has been in place since September 20, 2009 and no such problems have appeared.

### **The FSPTCA Characterizing Flavors Ban Does Not Discriminate Against Imports or Favor Domestic Products.**

As discussed above, there is no evidence of any discriminatory intent regarding the passage into law or implementation of either the entire FSPTCA or its characterizing flavor ban for cigarettes. The FSPTCA ban on cigarettes with characterizing flavors does not favor domestically produced cigarettes or domestic businesses or discriminate against imported cigarettes or foreign businesses.

The law's prohibition applies to any and all cigarettes with characterizing flavors other than tobacco or menthol without distinction as to whether they are imported or produced domestically – and the law's exception for cigarettes with characterizing flavors of tobacco or menthol apply across the board, with no distinctions as to whether they are imported or produced domestically. When the ban on characterizing flavors was first put into the FSPTCA legislation, and when the Act was finally passed into law, there were numerous domestically manufactured cigarette brands and sub-brands with characterizing flavors other than tobacco or menthol in existence between the time – and all of those domestic brands and sub-brands are now prohibited.<sup>32</sup>

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<sup>31</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, [http://archives.drugabuse.gov/NIDA\\_notes/NNVol18N2/Alternative.html](http://archives.drugabuse.gov/NIDA_notes/NNVol18N2/Alternative.html). 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>.

<sup>32</sup> Because the MSA applies only to cigarette companies that have signed onto the MSA – including all the major U.S. domestic cigarette manufacturers, which account for more than 90 percent of the entire U.S. cigarette market – the potential reach or impact of the 2006 MSA enforcement action against flavored cigarettes fell disproportionately on domestic cigarette

On the other hand, the FSPTCA characterizing flavor ban does not place any constraints on imports of any of the foreign-made brands and sub-brands of cigarettes with characterizing flavors of tobacco or menthol. All the foreign manufacturers and importers of menthol cigarettes benefit from menthol's exclusion from the FSPTCA's characterizing flavors ban just as the domestic manufacturers of menthol cigarettes do.

**It is Irrelevant that Most Manufacturers of Clove-Flavored Cigarettes are Located Outside of the United States in Indonesia and that Most Clove-Flavored Cigarettes Prior to the Ban were Imported.**

As noted above, the FSPTCA ban on cigarettes with characterizing flavors other than tobacco or menthol was passed into law purely for public health purposes, does not treat clove-flavored cigarettes differently from any other flavored cigarettes subject to the ban, makes no distinction between domestically manufactured cigarettes and imported cigarettes, and applies equally to domestically made and imported cigarettes. In particular, the FSPTCA provision has prohibited the sale of all clove-flavored cigarettes made in the United States, along with all other domestically manufactured cigarettes with characterizing flavors other than tobacco or menthol, and there was at least one domestic manufacturer selling clove-flavored cigarettes in the United States prior to the ban going into effect (Nat Sherman International, maker of "Touch of Clove" cigarettes).

Accordingly, it is irrelevant that prior to the ban going into effect imports accounted for a larger share of all clove-flavored cigarettes consumed in the United States than did domestically manufactured brands. That fact would be relevant only if the FSPTCA ban treated clove-flavored cigarettes more harshly than all of the other flavored cigarettes subject to the ban, or treated clove-flavored imports more harshly than clove-flavored cigarettes made domestically. But the FSPTCA provision has none of those characteristics.

**Because the FSPTCA Ban on Characterizing Flavors is Directed Solely at Reducing Tobacco Use and Its Harms and Was Passed Into Law Without Any Intent to Discriminate Against Imports, It Should Not Be Subject to Any WTO Action.**

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companies, most likely reducing the share of the U.S. market for cigarettes with characterizing flavors other than menthol consisting of domestic, as opposed to imported, cigarettes. But we have not been able to find any good data on the U.S. market share of cigarettes subject to the FSPTCA ban that were imported versus domestically made when the FSPTCA was debated and passed into law or when the characterizing flavor prohibition went into effect. Of the five major Indonesian cigarette companies -- Gudang Garam, HM Sampoerna, Djarum, Philip Morris Indonesia and Bentoel Internasional Investama – only Djarum is a participating MSA manufacturer subject to its restrictions and requirements. [National Association of Attorneys General (NAAG), *Participating Manufacturers under the Master Settlement Agreement as of July 27, 2010*, [http://www.naag.org/backpages/naag/tobacco/msa/participating\\_manu](http://www.naag.org/backpages/naag/tobacco/msa/participating_manu).] But it does not appear that Djarum voluntarily complied with the terms of the attorneys general settlement agreement with R.J. Reynolds that prohibited those flavored cigarette sales and marketing practices that violated the terms of the MSA (nor does it appear that any attorney general brought an MSA enforcement action to force Djarum to do so).

Should Indonesia's challenge to the FSPTCA ban on cigarettes with characterizing flavors come before a World Trade Organization dispute resolution panel, the panel should be reminded that the core justifications for liberalized trade that underlie the *General Agreement on Tariffs and Trade 1994*, the *Agreement on Technical Barriers to Trade*, and the World Trade Organization, itself – to make a wider variety of products more readily available to consumers, worldwide, at lower prices – simply do not apply at all to the trade in cigarettes and other tobacco products. Tobacco products are the only consumer products that cause serious harms to users (and, in the case of cigarettes and other combusted tobacco products to non-users exposed to the smoke), including premature death, even when used exactly as intended and expected. Unlike all other consumer products meant for human consumption, there is no safe, much less beneficial, level for consuming tobacco products. As a result, there are no social or economic benefits from liberalizing, expanding, or protecting international commerce in manufactured tobacco products. Instead of producing consumer benefits, any increases in the availability and affordability of tobacco products from liberalized trade will lead directly to more unnecessary disease, disability and death. Recognizing this fact, the Preamble to the Framework Convention on Tobacco Control states, before all else, that the parties to the convention are "[d]etermined to give priority to their right to protect public health," and 168 countries are parties that have signed the FCTC, with 154 also having formally ratified the Convention.<sup>33</sup>

More specifically, any action by a WTO dispute resolution panel to weaken or invalidate the FSPTCA provision banning cigarettes with characterizing flavors other than tobacco or menthol would work directly to increase tobacco use and its harms in the United States by making the provision and, therefore, the entire FSPTCA less effective. In addition, any ruling that including clove-flavored cigarettes in the FSPTCA's ban on flavored cigarettes, while not including menthol-flavored cigarettes, violates the *General Agreement on Tariffs and Trade* or the *Agreement on Technical Barriers to Trade* would almost certainly open the door to similar challenges relating to the foreign manufacture and import of any other type of flavored cigarette subject to the ban. Such a decision by a WTO panel might also put other provisions in the FSPTCA – and in other U.S. health laws – at risk of facing similar WTO challenges and rulings and could therefore undermine the ability of the United States to take effective action to protect the health and welfare of its citizens.

Indeed, a bad ruling by a WTO panel in this matter could establish a frightening WTO precedent that any action by a sovereign nation taken within its own borders to reduce tobacco use and its harms, or for any other public health purpose, is at serious risk of being struck down or weakened by WTO challenges if it treats different types of products within a broader product category differently -- even when the nation's actions are taken purely for public health purposes, with no discriminatory intent, when there are good reasons for the different treatment of different products within the broader category, and when imports of each of the different types of products are treated exactly the same as those manufactured domestically, with no evidence of any overall discriminatory impact. Such a ruling could create a chilling effect that could significantly impede and delay government efforts throughout the world to reduce tobacco use and its harms or otherwise protect and promote the public health.

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<sup>33</sup> As you know, the United States has signed but not yet ratified the FCTC. Indonesia has neither signed nor ratified the FCTC.

We hope that the information and references provided in this letter will help to prevent such a destructive WTO ruling and precedent. Please let us know if we might be of any further assistance.

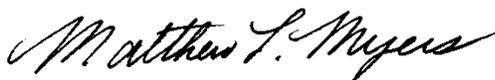
Sincerely,



Christopher W. Hansen  
President  
American Cancer Society Cancer Action Network



Nancy A. Brown  
Chief Executive Officer  
American Heart Association



Matthew L. Myers  
President  
Campaign for Tobacco-Free Kids



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