Litigation Update: Recent Cases that Implicate the Family Smoking Prevention and Tobacco Control Act

September 24, 2014

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Recognizing the ongoing health and economic burdens imposed by tobacco use,[1] Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) in 2009, granting the U.S. Food and Drug Administration (FDA) the jurisdiction to regulate tobacco products. In response to the Tobacco Control Act and the FDA's implementation of the Act, tobacco companies have brought multiple lawsuits challenging the constitutionality of the Act and of the FDA's regulations, the composition of the FDA's Tobacco Products Scientific Advisory Committee, and the preemptive scope of the Tobacco Control Act.

I. Challenges to Federal Laws and Regulations

Sottera Inc. v. U.S. Food and Drug Administration
627 F.3d 891 (D.C. Cir. 2011)

The FDA can only regulate e-cigarettes as a tobacco product, unless they are being marketed as a cessation device.

Background
On April 15, 2009, the FDA denied the import into the U.S. of electronic cigarettes and accessories made by Smoking Everywhere and NJOY. According to the FDA, these products appeared to be unapproved drug-device combination products that were intended to help treat the withdrawal symptoms of nicotine addiction.

Smoking Everywhere filed suit in the United States District Court for the District of Columbia, stating that electronic cigarettes are not intended to help treat withdrawal symptoms of nicotine addiction but, rather, that they are for smoking enjoyment, similar to conventional cigarettes. The court allowed NJOY to join the case with Smoking Everywhere. Both companies sought a preliminary injunction, which would prohibit the FDA from blocking their imports until the case has been decided.

The District Court's Decision
On January 14, 2010, the court granted the motion for preliminary injunction, and entered judgment in favor of Smoking Everywhere and NJOY. Judge Richard Leon ruled that Congress did not intend tobacco products to be drugs merely because they deliver nicotine—if this were true, traditional cigarettes would also be a drug-device combination product.[2] The court also found that the intended use of an electronic cigarette is to encourage nicotine use, rather than prevent or mitigate it.

The Court of Appeals' Decision
Senior Circuit Judge Stephen Williams affirmed the District Court's ruling that electronic cigarettes can be regulated solely as tobacco products, and not as drug-device combination products unless they are being marketed with a therapeutic purpose (cessation).[3]

Litigation Status
The FDA decided not to appeal the decision to the Supreme Court and instead issued a statement of its intent to regulate e-cigarettes as a tobacco product.[4]

Discount Tobacco City & Lottery, Inc. v. United States[5]
674 F.3d 509 (6th Cir. 2012)

The Tobacco Control Act's Graphic Warning and Other Requirements Upheld

Background
On August 31, 2009, six tobacco manufacturers and retailers filed suit in federal court in the U.S. District Court for the Western District of Kentucky to challenge the constitutionality of several parts of the Tobacco Control Act, including: 1) the graphic warning label requirement; 2) the modified risk tobacco product rule; 3) the prohibitions on event sponsorship, sampling, distribution of branded, non-tobacco merchandise, and continuity programs; 4) the prohibition on color/imagery in tobacco product advertising; and 5) the restriction on claims that a tobacco product is safe or safer as a result of FDA regulation. The companies argued that these provisions of the Tobacco Control Act violated their First Amendment rights. While the case moving through the D.C. Circuit, discussed below, challenges the specific graphic warning rule that the FDA passed under its authority granted by the Tobacco Control Act, this case challenges the provisions of the Tobacco Control Act itself.

The District Court's Decision
On January 5, 2010, the District Court upheld all challenged provisions of the Act as constitutional (under the case name *Commonwealth Brands, Inc. v. United States*), with the exception of the Tobacco Control Act's prohibition of color and imagery in advertising and the prohibition of statements implying that a tobacco product is safe or safer as a result of FDA regulation.[6] Both the tobacco companies and the government appealed this decision.

The Court of Appeals' Decision
On March 19, 2012, a three-judge panel of the U.S. Court of Appeals for the Sixth Circuit upheld most of the challenged restrictions as constitutional, largely affirming the District Court's prior decision.

The Court Upholds the Graphic Warning Label Requirement. The Court of Appeals held in a 2-1 decision that the graphic warning label requirement did not violate the First Amendment.[7] In making this determination, the majority of the court applied the *Zauderer* standard, based on the majority's characterization of the required graphic warnings as compelled disclosures of factual information, rather than restrictions on commercial speech.[8] The majority recognized that there are "myriad graphic images" that, like textual warnings, would provide "undisputed factual information about the health risks of using tobacco products."[9]

Under the *Zauderer* standard, disclosure requirements do not violate the First Amendment if they are reasonably related to the government's interest in preventing consumer deception.[10] The Court of Appeals determined that the government established a rational relationship between the

goal of preventing consumer deception and the warning label requirement based on: 1) the tobacco industry's extensive, documented history of deceiving the public about the health risks and addictiveness of smoking; 2) empirical evidence that existing warning requirements ineffectively convey the risks of tobacco use, particularly to youth as well as adults with low levels of education; and 3) scientific evidence that larger warnings incorporating imagery promote a greater understanding of tobacco-associated health risks.[11] Thus, the Court of Appeals held that the Tobacco Control Act's graphic warning requirement was permissible under the First Amendment.

The Court Upholds Other Challenged Provisions, with the Exception of the Prohibition on Continuity Programs and Color/Imagery in Advertising.

The Court of Appeals analyzed the remaining provisions challenged under the First Amendment using a different standard, the *Central Hudson* standard.[12] Under this standard, a restriction does not violate the First Amendment if it advances a substantial governmental interest and is no more restrictive than is necessary to achieve that interest.[13] Applying this standard, the court recognized that the government has substantial interests in reducing juvenile use of tobacco products and in ensuring that the health and safety claims made by tobacco companies are not misleading to consumers.[14] The court found that the Tobacco Control Act provisions prohibiting specific promotional activities, requiring FDA review of product health claims, and ensuring that tobacco companies do not claim that FDA regulation makes their products safer, directly serve one or both of these interests.[15] The court also recognized that the limits imposed by the Tobacco Control Act were generally no more restrictive than necessary to achieve the government's goals, especially given the close tie between promotional activities such as sampling, branded merchandise, and event sponsorship and juvenile use of tobacco products,[16] and the difficulties the government has encountered combating juvenile tobacco use and industry misinformation through alternative means.[17]

The restriction on any imagery and color being used in tobacco advertising, however, failed on this "no more restrictive than necessary" analysis. While the court recognized that such a restriction serves the government's substantial interest in "reducing the effects of tobacco advertising on juvenile consumers,"[18] the court also determined that the restriction was overbroad because it would apply to non-misleading, informative advertisements targeted at adults.[19] The restriction on continuity programs was also held to violate the First Amendment because the court found no evidence to support the government's argument that prohibiting these programs would advance the government's interest in reducing juvenile tobacco use, given that the "overwhelming beneficiaries, both numerically and comparatively, of these continuity programs are adult consumers."[20]

Litigation Status

The tobacco companies petitioned for a rehearing and a rehearing en banc (a rehearing with the full panel of Sixth Circuit judges, rather than the three-judge panel that issued the appellate court decision), both of which were denied on May 31, 2012. On October 26, 2012 the tobacco companies filed a Petition for Writ of Certiorari with the U.S. Supreme Court, requesting review of the Sixth Circuit's decision. The government filed its response, in opposition to Supreme Court review, on March 22, 2013. On April 22, 2013, the Supreme Court denied the tobacco industry's appeal to review the case, rendering the Court of Appeals' decision final.[21] Because

the Supreme Court has declined to hear the case, the FDA will retain the authority to promulgate a graphic warning rule in spite of the fact that the D.C. Circuit has struck down the FDA's actual rule. The next section discusses the case challenging the FDA's rule that establishes the content of the graphic warnings.

R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Administration
696 F.3d 1205 (D.C. Cir. 2012)

The FDA's Graphic Warning Rule Struck Down

Background
The Tobacco Control Act requires tobacco manufacturers to place new warnings that cover 50 percent of the surface of the front and rear of cigarette packages, as well as warnings covering 20 percent of the area of cigarette advertisements.[22] The Act requires that the warnings include color graphics, to be determined by the FDA, "depicting the negative health consequences of smoking."[23] The FDA released the final rule governing the new graphic warnings in June 2011 and scheduled the regulation to take effect in September 2012.

On August 16, 2011, five tobacco manufacturers (R.J. Reynolds, Lorillard, Commonwealth Brands, Liggett Group, and Santa Fe Natural) filed suit against the FDA in the U.S. District Court for the District of Columbia, challenging the FDA's graphic warning rule. The companies argued that the rule violated their First Amendment rights and that the warning requirements should have been put on hold until the case was fully resolved.

The District Court's Decision
The district court granted the tobacco companies' request to bar the rule from taking effect pending resolution of the case.[24] Additionally, on February 29, 2012, the district court held that the graphic warning rule violated the tobacco companies' First Amendment rights.[25] The FDA appealed this decision to the U.S. Court of Appeals for the D.C. Circuit.

The Court of Appeals' Decision
On August 24, 2012, a divided Court of Appeals affirmed the district court judgment striking down the FDA's graphic warning rule. In a 2-1 ruling, the Court of Appeals agreed with the district court that the requirements violated the tobacco companies' free speech rights guaranteed by the First Amendment.[26]

In determining that the graphic warning rule violated the First Amendment, the district court had applied a stringent standard, called "strict scrutiny," for analyzing the constitutionality of the rule. On appeal, the FDA challenged the district court's use of this standard. The Court of Appeals agreed with the FDA that the district court was incorrect in analyzing the graphic warning rule under the strict scrutiny standard, and instead the majority applied the more permissive *Central Hudson* standard.[27] Under this standard, a law or regulation restricting speech does not violate the First Amendment if the government can show that the law or regulation directly advances a substantial government interest, and the law is no more restrictive than is necessary to achieve the government's goal.[28]

In applying the *Central Hudson* standard, the majority found that the government's primary goal in adopting the graphic warning rule was to "discourage nonsmokers from initiating cigarette use and to encourage current smokers to consider quitting."[29] Although the majority conceded that the government's goal may be "a substantial interest," the court held that the rule was ultimately unconstitutional because the FDA failed to show that the graphic warning rule would directly advance this interest. The majority concluded that the FDA did not provide "a shred of evidence" that the graphic warnings would actually lower smoking rates.[30] That is, the court found that the FDA did not show "substantial evidence" that the graphic warnings would "directly" reduce smoking rates by a "material degree."[31] It found that there was "no evidence showing that [graphic] warnings have *directly caused* a material decrease in smoking rates in any of the countries that now require [large graphic warnings]."[32] Additionally, while "[s]ome Canadian and Australian studies indicated that large graphic warnings *might* induce individual smokers to reduce consumption, or to help persons who have already quit smoking remain abstinent," the studies "did not purport to show that the implementation of large graphic warnings has *actually* led to a reduction in smoking rates."[33]

It is important to note that the Court of Appeals decision was not unanimous. The dissenting judge would have upheld the rule under a different standard, the *Zauderer* test, which applies to compelled commercial speech, rather than using the *Central Hudson* standard, which applies to restrictions on commercial speech. The dissenting judge also disagreed with the majority's articulation of the government interest in the rule, finding that the real primary purpose of the graphic warning rule was to effectively communicate the negative health consequences of smoking to consumers.

Litigation Status

On October 9, 2012, the FDA filed a petition for a rehearing en banc (a rehearing before all of the judges of the U.S. Court of Appeals for the D.C. Circuit, instead of a three-judge panel), which was denied on December 5, 2012.

On March 15, 2013, Attorney General Eric Holder sent a letter to Speaker of the House John Boehner, advising that the U.S. government would not seek Supreme Court review of the Court of Appeals' decision, effectively ending this litigation. The FDA instead plans to develop and propose a new graphic warning rule.[34] Since then, a new study has been published suggesting that the FDA's analysis of the impact of graphic warning labels on smoking rates in Canada—an analysis that was important to the Court of Appeals' decision—vastly underestimated the likely impact of graphic warning labels on smoking rates in the U.S.[35]

U.S. v. Philip Morris USA, Inc.
686 F.3d 832 (D.C. Cir. 2012)

Tobacco Control Act Does Not Render RICO Remedies Moot

Background

On September 22, 1999, the U.S. Department of Justice (DOJ) sued several of the largest tobacco companies in federal district court for civil violations of the Racketeer Influenced and Corrupt Organizations Act (RICO).[36] On August 17, 2006, Judge Kessler of the U.S. District Court for the D.C. Circuit issued a 1,683-page opinion holding the tobacco companies liable for violating RICO due to their participation in a decades-long scheme to defraud the public about the health risks and addictiveness of smoking.[37] The district court determined that there was a reasonable likelihood that the companies would commit RICO violations in the future and imposed a set of restrictions that, among other things, prohibited the companies from making false or deceptive statements about cigarettes and their health impact and required disclosures of marketing and sales information to the public and the DOJ.[38] On May 22, 2009, the U.S. Court of Appeals for the D.C. Circuit largely affirmed the district court opinion and these remedies.[39]

In June 2009, the Tobacco Control Act was signed into law, granting the FDA comprehensive regulatory authority over the marketing, manufacture, and distribution of cigarettes and other tobacco products. One month later, the tobacco companies that were defendants in the original RICO case filed suit to vacate, or set aside, the requirements imposed by the 2006 decision, arguing that the Tobacco Control Act rendered the RICO remedies moot. On June 1, 2011, the district court rejected the tobacco companies' arguments, refusing to set aside the ruling.[40] The tobacco companies appealed.

The Court of Appeals' Decision

On July 27, 2012, the U.S. Court of Appeals for the D.C. Circuit affirmed the 2011 decision of the district court. First, the appeals court rejected the tobacco companies' argument that the Tobacco Control Act made the trial court's requirements irrelevant or unnecessary, finding that the Act's restrictions do not make it impossible for the companies to commit future RICO violations.[41] The court found that if the companies were not deterred by the penalties associated with RICO violations, there is no reason to believe they would be deterred by the restrictions imposed by the Act, which were not intended to address RICO violations.[42] Moreover, the court noted that relevant provisions of the Tobacco Control Act are the subject of ongoing litigation.[43] Even as the companies argue in this case that the Act will prevent them from violating RICO, the companies simultaneously try to limit their obligations under the Act by challenging its provisions, such as in *Discount Tobacco City & Lottery, Inc. v. United States*,[44] discussed above.

The appeals court also rejected the companies' argument that the district court should defer to the FDA, which now has primary authority over tobacco products, finding that the issue the requirements addressed – whether the defendants would commit future RICO violations – was within the expertise of the district court, not the FDA.[45] Furthermore, the Tobacco Control Act explicitly stated that it should not be interpreted to affect any pending legal action.[46]

Litigation Status

As a result of the U.S. Court of Appeals for the D.C. Circuit's decision, Judge Kessler's 2006 opinion and the majority of the requirements it imposed on the major tobacco companies, such as the requirement to make corrective statements in the press, continue to be valid, despite the tobacco companies' repeated attempts to escape consequences for its behavior.

On October 15, 2012, Judge Kessler heard the tobacco industry's objections to the Justice Department's proposed "corrective statements" previously ordered by the court as a remedy for the industry's years of fraudulent statements about the dangers of smoking. The tobacco industry argued that the proposed corrective statements would violate the First Amendment rights of the tobacco companies because they would force the companies to acknowledge their own wrongdoing, instead of simply requiring the companies to make generic statements of the harm from smoking. However, on November 27, 2012, Judge Kessler rejected these arguments, instead finalizing the text of the "corrective statements" and ordering the parties to confer with a "special master" (a person, usually an attorney, appointed by the court) to reach an agreement as to how the tobacco companies must implement the order and communicate these statements to the public.[47] The tobacco companies appealed Judge Kessler's corrective statement order to the U.S. Court of Appeals for the D.C. Circuit; the appeal is in abeyance pending the district court's resolution of the implementation issues.[48]

Lorillard, Inc. v. U.S. Food & Drug Administration
No. 11-440 (RJL), 2012 WL 3542228 (D.D.C. Aug. 1, 2012)

Tobacco Product Scientific Advisory Committee Composition Can Be Challenged

Background
On February 21, 2011, Lorillard and R.J. Reynolds filed suit in the U.S. District Court for the District of Columbia to challenge the composition of the FDA's Tobacco Product Scientific Advisory Committee (TPSAC). TPSAC was formed as required by the Tobacco Control Act to advise the FDA on safety and health issues relating to tobacco products.[49] By filing this suit, the tobacco companies seek to discredit TPSAC's report on the health effects of menthol, which concluded that removing menthol cigarettes from the market would benefit public health. The manufacturers also seek to prevent any further work of TPSAC on the issue of dissolvable tobacco products, tobacco product standards, and other matters until the membership of TPSAC is changed to address the companies' concerns.

The tobacco companies claim that three members of TPSAC have conflicts of interest that would prevent them from providing impartial analyses and recommendations to the FDA regarding tobacco products.[50] The TPSAC members are allegedly conflicted because they previously made statements in support of tobacco control measures, continue to serve as expert witnesses in litigation against tobacco manufacturers, and serve as consultants for pharmaceutical companies that manufacture smoking-cessation products.[51] The manufacturers also allege that the composition of TPSAC does not reflect a fair balance of viewpoints, as required by the Federal Advisory Committee Act, claiming that the committee is controlled by a clique of people with similar viewpoints on smokeless tobacco, menthol, and other major tobacco-related issues.[52]

The FDA moved to dismiss the suit on several grounds, including that the tobacco companies do not have standing, or the ability to bring a suit, because they have not alleged harm stemming from TPSAC's membership that is more than speculative (particularly because the FDA is not bound to follow TPSAC's recommendations). The FDA also argued that it had adhered to the membership requirements outlined by the Tobacco Control Act and that it is not the place of the

court to arbitrarily substitute its judgment for the FDA's and make subjective determinations as to which views on tobacco control merit representation. As to the conflict of interest claim, the FDA argued that the agency has discretion to enforce conflict of interest rules, so the issue is not reviewable by the court.

The District Court's Decision

On August 1, 2012, ruling on the FDA's motion to dismiss the suit, Judge Richard Leon rejected all of the FDA's arguments, noting, in particular, that the court has sufficient standards with which to evaluate the agency's exercise of discretion regarding the fair balance of views on the committee, due to the "limited number of viewpoints" on tobacco control issues and "the scientific—as opposed to political—nature of those viewpoints."[53] The court also disagreed with the FDA and determined that the tobacco companies had alleged sufficient injury, including loss in shareholder value, disclosure of economic information to potentially conflicted TPSAC members, and violation of their "procedural right to 'fair decision-making.'"[54]

On June 21, 2013, the FDA filed a motion for summary judgment, once again challenging the tobacco companies' standing to bring suit and arguing that the focus on scientific expertise in selecting TPSAC members and compliance with the Tobacco Control Act's membership criteria satisfies the "fair balance" requirement of the Federal Advisory Committee Act ("FACA").[55] The FDA also argued that even if reviewable by a court, no conflicts violations occurred because the FDA appropriately reviewed potential conflicts within the scope of its discretion.[56] The tobacco industry responded with its own motion for summary judgment and opposition to the FDA's motion on July 19, 2013.[57] In the motion, the tobacco industry set forth its factual basis for standing and its claims.

On July 21, 2014, Judge Leon granted the tobacco industry's summary judgment motion, stating that the FDA erred in concluding that the three challenged members of the TPSAC did not have financial and appearance conflicts of interest.[58] Accordingly, their appointment to the panel was arbitrary and capricious in violation of the Administrative Procedure Act and fatally tainted the composition of the board, including the menthol report.

Because Judge Leon decided that the conflicts of interest was enough to taint the TPSAC committee, he did not address the fair balance and special interest claims that were also brought by the tobacco companies.[59]

In concluding that the three challenged members had financial conflicts, Judge Leon was most concerned with prior consulting work as well as potential profits from the purchase of cessation products.[60] Dr. Neal Benowitz consulted for several companies, including Pfizer, a firm that provided him with grant support and for whom Dr. Benowitz authored a study. Dr. Jack Henningfield has consulted in the past and continued to consult for GlaxosmithKline (GSK) while on TPSAC. Dr. Jonathan Samet received grant support from GSK at least six times in the past, and also received annual honoraria from Pfizer for his work on Pfizer's Global Tobacco Advisory Board. Judge Leon determined these facts to be enough to create financial conflicts of interest.[61] Judge Leon concluded that the TPSAC members stood to benefit from the potential uptick in use of smoking cessation products, which would then lead to pharmaceutical companies requiring more consulting work from the doctors.

Additionally, Judge Leon found that TPSAC member's testimony, and importantly their potential to continue testifying for tobacco control policies, created an appearance conflict of interest.[62] Accordingly, Judge Leon stated "the only way the agency can correct its error of law in evaluating the credential of future members of the TPSAC is for this Court to remand the case to the agency for the appointment of a newly-constituted, interest free, TPSAC panel of authorities consistent with the applicable ethics laws."

Litigation Status

An appeal of this decision is pending before the U.S. Court of Appeals for the D.C. Circuit.

II. Challenges to Local Laws and Regulations

In addition to challenges to the FDA's authority and its regulations, the tobacco industry has also attempted to use the Tobacco Control Act's narrow preemption provision as a weapon to fight strong tobacco control policies at the local level.

23-34 94th St. Grocery v. N.Y.C. Board of Health
685 F.3d 174 (2d Cir. 2012)

NYC's Graphic Warning Requirement Struck Down

Background
In 2009, the New York City Board of Health adopted a resolution requiring tobacco retailers to post signs that graphically depict the adverse health effects of tobacco use and provide information about cessation services. The graphic warnings that were implemented focused solely on the adverse health effects of smoking. On June 2, 2010, two cigarette retailers, two trade associations, and three of the country's largest cigarette manufacturers sued New York City in the U.S. District Court for the District of New York, claiming that the resolution was preempted by – or prohibited by – federal law.

Congress included preemption language in the Federal Cigarette Labeling and Advertising Act (FCLAA), which provides, "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provision of this chapter."[63] This portion of FCLAA was modified in 2009 by the Tobacco Control Act to allow state and local laws that restrict the time, place, and manner but not the content, of cigarette advertisements and promotions.[64]

The District Court's Decision
The district court found that New York City's signage requirement was preempted by FCLAA.[65] The city appealed.

The Court of Appeals' Decision
On July 10, 2012, the U.S. Court of Appeals for the Second Circuit upheld the district court's decision that struck down the Board of Health resolution on the basis that it was preempted – or prohibited by – FCLAA. The city argued that the warning sign requirement was a restriction on the sale, not the promotion, of cigarettes because the resolution required signs wherever cigarettes were sold, regardless of advertising or promotion within an establishment. The appellate court, however, found that the signage requirement affected the display of cigarettes, which is a type of promotion. The court also was concerned that allowing local authorities to post supplemental warnings on or near cigarette displays risks creating diverse, nonuniform, and confusing regulations in the context of the Tobacco Control Act's graphic warning requirement.

The court clarified that not all state and local regulations related to cigarette promotion are preempted, given FCLAA's exemption for state and local regulations that restrict the time, place, and manner but not content, of cigarette promotion. The court found that the exemption did not apply to the New York City Board of Health resolution because it affected the content of manufacturers' promotional messages and it applied "wherever" tobacco products are sold, which it found was not a lawful restriction on the "place" of tobacco product promotion.[66]

Litigation Status
The New York City Board of Health did not appeal this decision to the United States Supreme Court.

U.S. Smokeless Tobacco Manufacturing Company, LLC v. City of New York
708 F.3d 428 (2d Cir. 2013)

NYC's Law Prohibiting the Sale of Flavored Tobacco Products Upheld

Background
In October 2009, a New York City ordinance was enacted, prohibiting the sale of flavored, non-cigarette tobacco products (other than menthol) in all places within the city, except in certain tobacco bars. U.S. Smokeless Tobacco filed a complaint with the U.S. District Court for the Southern District of New York, arguing that the city's ordinance was preempted by the Tobacco Control Act. The tobacco company argued that the ordinance set a "tobacco product standard," which is an authority reserved to the FDA under the Act. In January 2010, the company filed a motion for preliminary injunction with the court, asking it to put enforcement of the law on hold while the litigation was pending. The court issued a decision on March 2010, finding that it was "highly unlikely" that the tobacco company would prevail on the merits of the case, and denied the motion.[67] The tobacco company and NYC filed motions for summary judgment with the court agreeing that there were no factual issues in dispute and asking the court to rule in each party's favor.

The District Court's Decision
On November 15, 2011, the court granted NYC's motion, and entered judgment in favor of the city. Judge McMahon found that the language of the Tobacco Control Act indicates no intention to take away state and local authority to regulate the sale or distribution of tobacco products.

The court made clear that the Act gives the federal government exclusive control over tobacco product manufacturing standards, while allowing state or local governments to make laws regulating the sale or distribution of tobacco products.[68]

The court also found that the Act allows state and local governments to enact restrictions on tobacco products that are more stringent than federal regulations and thus NYC's restriction on flavored tobacco products was not preempted by the Act.[69]

The Court of Appeals' Decision
On February 26, 2013, the U.S. Court of Appeals for the Second Circuit upheld the district court's ruling. This court found that a state or local government regulation imposing a sales prohibition on a class of products was not preempted by the Tobacco Control Act.[70]

Although the NYC ordinance was not a complete prohibition, as it allowed the sale of flavored products in tobacco bars, the court ruled that even a complete prohibition on a class of products would not necessarily be preempted. The court found that a sales prohibition would only be preempted if the regulation imposed a product standard, a power reserved to the FDA. A sales prohibition would only create a product standard if the regulation prohibited the sale of a class of products that was manufactured in a particular way or with particular ingredients. However, a sales prohibition that merely references the characteristics of an end product does not create an impermissible product standard.[71]

Litigation Status
On March 8, 2013, the tobacco companies appealed for a rehearing and a rehearing en banc (a rehearing with the full panel of Second Circuit judges, rather than the three-judge panel that issued the appellate court decision) which was denied on May 1, 2013. No appeal was filed with the Supreme Court by the July 29, 2013 deadline to appeal, rendering the Court of Appeals' decision final.

National Association of Tobacco Outlets, Inc. v. City of Providence
731 F.3d 71 (1st Cir. 2013)

Providence's Law Prohibiting the Redemption of Coupons and the Sale of Flavored Tobacco Products Upheld

Background
On January 5, 2012, the city of Providence enacted two tobacco control ordinances, one to prohibit the redemption of coupons (pricing ordinance) and one to prohibit the sale of flavored non-cigarette tobacco products (flavor ordinance). On February 13, 2012, an association of tobacco retailers, an association of cigar manufacturers and seven tobacco product manufacturers filed suit in the U.S. District Court for the District of Rhode Island alleging that the two ordinances were preempted by the Tobacco Control Act, were in violation of the Rhode Island and U. S. Constitutions, and were an unlawful deprivation of civil rights.[72] The tobacco industry argued that the Providence coupon restriction governed "cigarette promotion," which is preempted by FCLAA, and that the flavored product restriction set a "product standard," which

is a power reserved to the FDA by the Tobacco Control Act.[73] Both sides filed motions for summary judgment and the court held a hearing on August 22, 2012 to hear testimony.

The District Court's Decision

On December 10, 2012, Judge Lisi dismissed the tobacco industry's motion and granted the city's motion upholding both of Providence's ordinances. The court found that the city's pricing ordinance was not preempted by FCLAA, as amended by the Tobacco Control Act, and that the flavor ordinance also was not preempted by the Tobacco Control Act. Specifically, the court held that the pricing ordinance does not impose additional requirements on labeling and advertising of cigarettes or the content of promotional materials but merely regulates the sale of cigarettes. This puts the restriction squarely in the category of conduct that is excluded from FCLAA's preemption provision.[74] In deciding whether or not the flavor ordinance was preempted, the court partially relied on the opinion in *U.S. Smokeless Tobacco Manufacturing Company, LLC v. City of New York*, and came to the same conclusion: the flavor ordinance did not create a product standard which is preempted by federal law; rather it imposed a restriction on the sale of tobacco products, which is not preempted.[75] The tobacco industry appealed the decision to the U.S. Court of Appeals for the First Circuit.

The Court of Appeals' Decision

On September 30, 2013, the U.S. Court of Appeals for the First Circuit affirmed the district court's ruling that neither the pricing ordinance or flavor ordinance were preempted by federal law.[76] The court relied on previous court of appeals decisions in other circuits for the assumption that the activities regulated by the pricing ordinance were "promotion." Nonetheless, the court held that the pricing ordinance's restrictions fell under FCLAA's exception for content-neutral, "time, place, or manner" restrictions on promotion. The court determined that to qualify as a "content" restriction a regulation must relate to health claims or specific health information requirements, which the pricing ordinance did not.[77] Further, the court declared that regulating coupons and multi-pack discounts did not materially differ from regulating the "manner" of promotion through price restrictions (such as minimum price laws) that the tobacco industry had conceded were excluded from FCLAA preemption.[78]

The Court of Appeals also ruled that the flavor ordinance did not effectively create a preempted tobacco product standard by banning non-cigarette flavored tobacco products because their sale was still permitted in smoking bars. The court also emphasized the absence of an outright prohibition in determining that the flavor fell under the Tobacco Control Act's "savings clause" that specifically exempts regulations "relating to" the sale of tobacco products from preemption.[79]

Litigation Status

The National Association of Tobacco Outlets applied for, and was granted, an extension of the period to petition for appeal to the U.S. Supreme Court—extending the period for appeal to February 27, 2014.[80] The Association did not, however, file a petition for appeal to the Supreme Court[81] and did not file a petition for rehearing by the 1st Circuit en banc, rendering the Court of Appeals' decision final.

National Association of Tobacco Outlets, Inc. v. City of New York
No. 14 CV577 (TPG)(JCF), 2014 WL 1354901 (S.D.N.Y. Jun. 18, 2014)

NYC Ordinance Prohibiting the Use of Coupons and Discounts for Tobacco Products Upheld

Background
In November 2013, New York City enacted an ordinance regulating the tobacco industry's use of promotional pricing strategies. Among other prohibitions, the law restricts the sale of tobacco products below the advertised price, sets a price floor for cigarettes and little cigars, and prohibits multi-pack discounts. In January 2014, three tobacco retail store associations and six tobacco product manufacturers filed suit against the City of New York with the U.S. District Court for the Southern District of New York, challenging the ordinance's prohibition on the sale and offer to sell tobacco products below the listed price. The industry argued that the ordinance violated their First Amendment right to commercial speech and that it was preempted by both federal and state law.

Both parties filed a stipulation which stayed enforcement of the challenged provisions in the ordinance until May 23, 2014, which the court later extended until June 20, 2014. Both parties also filed for summary judgment. The industry argued that the ordinance unlawfully restricts its First Amendment right by restricting its ability to communicate discount pricing and deal information to consumers. It also contended that the Federal Cigarette Labeling and Advertising Act (FCLAA) preempted the ordinance's restriction on pricing content in advertisements and promotions.[82] Finally, the tobacco industry claimed the New York State Public Health Law preempted the ordinance, arguing the statute sanctioned its pricing strategies and reserved the right to regulate the distribution of free tobacco products.[83]

The District Court's Decision
The district court granted the City of New York's motion for summary judgment in its entirety. Judge Thomas Griesa held that the ordinance did not violate the First Amendment, and that neither federal nor state laws preempted its enactment.

The court ruled the ordinance merely regulated an economic transaction; to violate the First Amendment, the ordinance would have to restrict the dissemination of pricing information. In determining this, the court relied on the First Circuit's decision in *National Association of Tobacco Outlets, Inc. v. City of Providence*, which came to a similar conclusion.[84]
The court also held the ordinance did not violate either FCLAA or the New York State Public Health Law. Relying on Congress' 2009 amendment to FCLAA, which allows states and localities to pass restrictions on the "time, place, and manner, but not the content, of the advertising or promotion of any cigarettes," the court found that the ordinance lawfully regulated only the manner of such promotion and did not apply to promotional content.[85] The court also noted that FCLAA only addressed regulation of health information in advertisements and promotions, not pricing information.[86]Judge Griesa also found the New York State Public Health Law did not preempt the city's ordinance because the state law was not intended to sanction the industry's coupon and discount strategies, nor did it pertain to the regulation of free distribution of tobacco products. The ordinance thus withstood each challenge from the tobacco industry.

Litigation Status
The case was decided on June 18, 2014. The industry may appeal the decision to the Second Circuit Court of Appeals within 30 days of the judgment's entry.[87] If no such appeal is filed within that time, the district court's decision is final.

III. International Trade Dispute

United States – Measures Affecting the Production and Sale of Clove Cigarettes World Trade Organization, Dispute Settlement DS406

Flavored Cigarette Prohibition Inconsistent with WTO Trade Agreement

Background
Section 907 of the Food Drug and Cosmetic Act, as amended by the Tobacco Control Act prohibited the production and sale of cigarettes with "characterizing flavors," including fruit, chocolate, cinnamon, and clove flavors.[88] The stated objective of this prohibition was "to protect the public health, including by reducing the number of children and adolescents who smoke cigarettes" by "prohibit[ing] the manufacture and sale of cigarettes with certain 'characterizing flavors' that appeal to youth."[89] Significantly, menthol cigarettes were specifically exempted from the flavoring prohibition.[90] The practical result was that the sale of clove cigarettes, which are largely imported from Indonesia, was prohibited in the United States while the sale of menthol cigarettes, which are largely produced by domestic tobacco manufacturers and represent about a quarter of the U.S. cigarette market, remained legal.[91] In response to this situation, Indonesia filed a complaint with the World Trade Organization (WTO) in 2010, alleging that section 907 violated international trade agreements by discriminating against flavored tobacco products made in other countries.[92] The dispute was referred to a panel established by the WTO's Dispute Settlement Body (DSB).

The WTO's Decision
In 2011, the DSB found in favor of Indonesia, determining that section 907 was "inconsistent" with a provision of the WTO Agreement on Technical Barriers to Trade (TBT), which requires member nations to treat products made in other WTO member countries no less favorably than "like" products of domestic origin.[93] The panel also found that the U.S. violated procedural requirements of the TBT by failing to notify WTO members of products to be covered by section 907 prior to the enactment of the Tobacco Control Act and by providing only three months between publication and entry into force of the prohibition.[94]

The U.S. appealed, but on April 4, 2012 the WTO's appellate body issued a report upholding the panel's conclusions,[95]a report that was adopted by the DSB on April 24, 2012.[96] One of the U.S.'s arguments on appeal was that menthol and clove cigarettes are not "like" products.[97] The appellate body disagreed, determining that the products are in a sufficiently competitive relationship to be "like," based on their similar physical characteristics and tariff classification, ability to serve similar end-uses (e.g. satisfying addiction, creating a "pleasurable experience"),

and high degree of substitutability for a segment of U.S. consumers (young and novice smokers).[98]

While the appellate body recognized section 907's aim of reducing youth smoking as "a legitimate objective,"[99] the appellate body questioned whether 907 actually operates to serve this aim because "menthol cigarettes have the same product characteristic that, from the perspective of the stated objective of Section 907(a)(1)(A), justified the prohibition of clove cigarettes" – namely a flavor that masks the harshness of tobacco, making cigarettes more palatable to inexperienced smokers.[100] The appellate body also rejected the United States' argument that the exemption of menthol was created to address legitimate regulatory concerns, unrelated to national origin: 1) that prohibiting a product used by millions of smokers will overwhelm the health system with nicotine addicts experiencing withdrawal symptoms, and 2) that a prohibition would lead to an increase in smuggling and illicit sales of menthol cigarettes.[101] The appellate body did not find these arguments credible, stating that "it is not clear that the risks that the United States claims to minimize by allowing menthol cigarettes to remain in the market would materialize if menthol cigarettes were to be banned, insofar as regular cigarettes [which, like menthol cigarettes, contain nicotine] would remain in the market."[102]

On May 24, 2012, the U.S. made a statement to the DSB indicating it "intends to implement the recommendations and rulings of the [Appellate Body] in a manner that protects public health and respects the obligations of the United States under the WTO Agreement."[103] However, the U.S. also reiterated its stance that prohibiting clove and other flavored cigarettes would benefit public health by reducing the likelihood that youth would start smoking.[104] On June 14, 2012, Indonesia and the U.S. agreed that the U.S. would have until July 24, 2013 to implement the appellate body's rulings.[105]

On July 23, 2013, the U. S. provided a status report to the DSB in which it claimed that it was implementing the recommendations and rulings of the DSB by publishing an Advanced Noticed of Proposed Rulemaking (ANPRM) relating to menthol in cigarettes by the FDA, releasing a scientific evaluation of menthol in cigarettes by the FDA, announcing a youth education campaign targeting menthol cigarettes, sharing cessation tools through BeTobaccoFree.gov, and educating the public about menthol cigarettes through SmokeFree.gov.[106] In addition, the U.S. noted that the "statement today was quite clear in that we have taken measures to come into compliance," and that "our view is that we will not need to revert to this item."[107]

Indonesia was not satisfied with the U.S. actions and on August 12, 2013, asked the DSB to allow Indonesia to impose trade sanctions on the U.S.[108] Indonesia has set the value of its proposed retaliation at over $40 million per year.[109] However, the U.S. objected to Indonesia's request for sanctions and the matter was referred to arbitration on August 23, 2013.[110]

In arbitration, the U.S. has raised a number of arguments against sanctions, including that the U.S. has brought section 907 into compliance with trade agreement requirements by: (1) conducting and publishing further scientific evaluation of the "public health implications of menthol cigarettes," which demonstrates that there is a "legitimate regulatory distinction between menthol and clove cigarettes; (2) issuing the menthol ANPRM,[111] which will permit the U.S. to further develop its understanding of the public health implications of menthol cigarettes; and (3)

applying provisions of the Tobacco Control Act in an "even-handed manner," considering the "different regulatory challenges" presented by menthol and clove cigarettes.[112] The U.S. also disputes Indonesia's calculation of sanctions, arguing, among other things, that Section 907 has not caused a decrease in Indonesia's export of clove cigarettes because at least one major brand of Indonesian clove cigarettes has "adapted" so that it can avoid Section 907 and continue to be imported to the U.S.[113]

On June 24, 2014, the U.S. and Indonesia jointly requested a suspension of the arbitration proceedings which prevents the arbitrator's decision from being publicly released.[114] The decision will remain confidential indefinitely until one of the parties terminates the agreement to suspend the arbitration proceedings.

While the WTO's decision can be perceived as a threat to the ability of nations to institute health-protective tobacco control regulations, the WTO was careful to clarify that its decision was not to be interpreted as prohibiting WTO member nations from instituting tobacco control measures, or even from specifically implementing restrictions on ingredients that make tobacco products more attractive to young smokers.[115] While the United States *can* prohibit clove cigarettes, it cannot do so in a manner that seems to give more favorable treatment to "like" domestic products – in this case, menthol flavored cigarettes.[116]

Notes

[1] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2(1)–(2), (6)–(7), (13)–(14), 123 Stat. 1776, 1777 (codified in scattered sections of 21 U.S.C.).

[2] Smoking Everywhere, Inc. v. U.S. Food and Drug Admin., No. 09-771 (D.D.C. Jan. 14, 2010).

[3] Sottera, Inc. v. U.S. Food and Drug Admin., 627 F.3d 891 (D.C. Cir. 2011).

[4] U.S. Food and Drug Admin., *Stakeholder Letter: Regulation of E-Cigarettes and Other Tobacco Products* (April 25, 2011), http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm.

[5] This document will refer to this case as *Discount Tobacco*, the name under which the Court of Appeals heard the case. The district court decision in this case is known as *Commonwealth Brands*.

[6] Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

[7] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 569 (6th Cir. 2012).

[8] *Id*. at 561 (citing Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985)).

[9] *Disc. Tobacco*, 674 F.3d at 560.

[10] For more information about the *Zauderer* standard, refer to TOBACCO CONTROL LEGAL CONSORTIUM, REGULATING TOBACCO MARKETING: "COMMERCIAL SPEECH" GUIDELINES FOR STATE AND LOCAL GOVERNMENTS 6–7 (2010), *available at* http://publichealthlawcenter.org/sites/default/files/resources/tclc-guidelines-speech-2010.pdf.

[11] *Disc. Tobacco*, 674 F.3d at 562–64.

[12] *Id*. at 533, 539, 548, 550 (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980)).
[13] *Id.* at 522–32; *see supra* note 9 for more information regarding the *Central Hudson* standard.
[14] *Disc. Tobacco*, 674 F.3d at 534, 539, 541, 550.
[15] *Id.* at 536, 541, 551.
[16] *Id.* at 541–43.
[17] *Id.* at 537.
[18] *Id.* at 548.
[19] *Id.* at 547–48.
[20] *Id.* at 544.
[21] Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).
[22] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201(a), 123 Stat. 1776, 1842–44 (amending 15 U.S.C. § 1333(a)-(b) (2006)).
[23] *Id.* § 201(a), 123 Stat. at 1845 (amending 15 U.S.C. § 1333(d) (2006)).
[24] R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 823 F. Supp. 2d 36, 53 (D.D.C. 2011).
[25] R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 845 F. Supp. 2d 266, 277 (D.D.C. 2012).
[26] R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205 (D.C. Cir. 2012). Dissenting Judge Rogers concluded that the graphic warnings, except the requirement that they include "1-800-QUIT-NOW," were constitutional. *Id.* at 1223.
[27] *Id.* at 1217.
[28] For more information about the *Central Hudson* standard, refer to TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 10, at 5–6.
[29] *R.J. Reynolds*, 696 F.3d at 1218 (quoting Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011)).
[30] *Id.* at 1219.
[31] *Id.* at 1219–20.
[32] *Id.* at 1219.
[33] *Id.*
[34] For a more in-depth examination of the distinctions between *Discount Tobacco* and *R.J. Reynolds* and the FDA's options for implementing a graphic warning rule, *see* TOBACCO CONTROL LEGAL CONSORTIUM, CIGARETTE GRAPHIC WARNINGS AND THE DIVIDED FEDERAL COURTS (2013) *available at* http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-ciggraphicwarnings-dividedfedcts-2013.pdf.
[35] Jidong Huang, Frank Chaloupka & Geoffrey T. Fong, *Cigarette Graphic Warning Labels and Smoking Prevalence in Canada: A Critical Examination and Reformulation of the FDA Regulatory Impact Analysis*, 23 suppl. 1 TOBACCO CONTROL i7 (2014). For a summary of the study and its implications for the FDA's implementation of graphic warnings, see Campaign for Tobacco Free Kids, *New Study: FDA Vastly Underestimated How Much Graphic Cigarette Warnings Would Reduce Smoking in U.S: Statement of Matthew L. Myers President, Campaign for Tobacco-Free Kids* (Nov. 25, 2013), http://www.tobaccofreekids.org/press_releases/post/2013_11_25_warnings.
[36] For more information on this case, *see* TOBACCO CONTROL LEGAL CONSORTIUM, EVERYTHING YOU EVER WANTED TO KNOW ABOUT *U.S. V. PHILIP MORRIS* BUT WERE AFRAID TO ASK (2013) *available at* http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-DOJ-litigation-overview-2013.pdf; TOBACCO CONTROL LEGAL CONSORTIUM, THE VERDICT IS IN: FINDINGS FROM *UNITED STATES V. PHILIP MORRIS* (2006) *available at* http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf.

[37] United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1 (D.D.C. 2006).
[38] *Id.*
[39] United States v. Philip Morris USA, Inc., 566 F.3d 1095, 1150 (D.C. Cir. 2009).
[40] United States v. Philip Morris USA, Inc., 787 F. Supp. 2d 68 (D.D.C. 2011).
[41] United States v. Philip Morris USA, Inc., 686 F.3d 832, 836–37 (D.C. Cir. 2012).
[42] *Id.* at 837.
[43] *Id.*
[44] Disc. Tobacco City & Lottery, Inc. v. U.S., 674 F.3d 509 (6th Cir. 2012).
[45] *Philip Morris*, 686 F.3d at 837–38.
[46] *Id.* at 838.
[47] United States v. Philip Morris USA, Inc., No. 99-2496 (D.D.C. Nov. 27, 2012).
[48] United States v. Philip Morris USA, Inc., No. 13-5028 (D.C. Cir. Feb. 15, 2013).
[49] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 101, 123 Stat. 1776, 1824–25 (amending 21 U.S.C. §387(q) (2006)).
[50] Second Amended Complaint for Declaratory and Injunctive Relief ¶¶ 2, 129–40, Lorillard, Inc. v. U.S. Food & Drug Admin., No. 11-440 (RJL), 2012 WL 3542228 (D.D.C. Aug. 1, 2012), 2011 WL 2790624.
[51] *Id.* ¶¶ 2, 51-75, 109–11.
[52] *Id.* ¶¶ 94-108.
[53] *Lorillard*, 2012 WL 3542228, at *2.
[54] *Id.*
[55] Memorandum in Support of Defendants' Motion for Summary Judgment at 18–25, *Lorillard*, 2012 WL 3542228 (No. 11-440 (RJL).
[56] *Id.* at 25–27.
[57] Redacted Memorandum in Support of Plaintiffs' Motion for Summary Judgment and in Opposition to Defendants' Motion for Summary Judgment, *Lorillard*, 2012 WL 3542228 (No. 11-440 (RJL).
[58] Lorillard Inc. et al. v. United States Food and Drug Administration, No. 11-440 (July 21, 2014).
[59] *Id.* at 4.
[60] *Id.* at 28.
[61] *Id.* at 29-30.
[62] *Id.* at 33.
[63] 15 U.S.C. § 1334(b) (2012).
[64] *Id.* § 1334(c).
[65] 23-34 94th St. Grocery Corp. v. N.Y.C. Bd. of Health, 757 F. Supp. 2d 407 (S.D.N.Y. 2010).
[66] 23-34 94th St. Grocery Corp. v. N.Y.C. Bd. of Health, 685 F. 3d 174, 184 n.9 (2d Cir. 2012).
[67] U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 703 F. Supp. 2d 329, 343 (S.D.N.Y. 2012).
[68] *Id.* at 344
[69] *Id.* at 345
[70] U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 708 F.3d 428 (2d Cir. 2013).
[71] *Id.* at 435.
[72] Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, No. 12-96-ML, 2012 WL 6128707 (D.R.I. Dec. 10, 2012).
[73] *Id.* at *10–11.
[74] *Id.* at *11.
[75] *Id.* at *12–13 (citing 703 F. Supp. 2d 329, 340 (S.D.N.Y. 2010)).
[76] Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, 731 F.3d 71 (1st Cir. 2013).

[77] *Id.* at 80.
[78] *Id.* at 81.
[79] *Id.* at 82–83.
[80] National Ass'n of Tobacco Outlets, Inc. v. City of Providence, Docket No. 13A626 (last modified Dec. 19, 2013), http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/13a626.htm.
[81] *Id.*
[82] 15 U.S.C. § 1334(c).
[83] New York State Public Health Law Article-F-Regulation of Tobacco Products, Herbal Cigarettes and Smoking Paraphernalia; Distribution to Minors, § 1339-bb.
[84] Nat'l Ass'n Tobacco Outlets, Inc. v. City of Providence, 731 F.3d 71 (1st Cir. 2013).
[85] 15 U.S.C. § 1334(c).
[86] 15 U.S.C 1339.
[87] FED. R. APP. P. 4(a)(1)(A).
[88] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 101, 123 Stat. 1776, 1824–25 (amending 21 U.S.C. 387(g)(a)(1)(A) (2006)).
[89] H.R. REP. NO. 111-58(I), at 37 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 486.
[90] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 101, 123 Stat. 1776, 1824–25 (amending 21 U.S.C. 387(g)(a)(1)(A) (2006)).
[91] Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, ¶¶ 222–23, WT/DS406/AB/R (Apr. 4, 2012) (*adopted* Apr. 24, 2012) [hereinafter Appellate Body Report] *available at* http://www.wto.org/english/tratop_e/dispu_e/406abr_e.pdf.
[92] Request for the Establishment of a Panel by Indonesia, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/2 (June 11, 2010), *available at* http://www.worldtradelaw.net/pr/ds406-2%28pr%29.pdf.
[93] Panel Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, ¶¶ 7.293, 8.1(b), 8,6, WT/DS406/R (Sept. 2, 2011) (*adopted* Apr. 24, 2012), *available at* http://www.worldtradelaw.net/reports/wtopanels/us-clovecigarettes%28panel%29.pdf.
[94] *Id.* ¶¶ 7.550, 7.551, 7.595, 8.1(f)–(h), 8.6.
[95] Notification of an Appeal by the United States, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/6 (Jan. 10, 2012), *available at* http://trade.ec.europa.eu/doclib/docs/2013/january/tradoc_150276.pdf; Appellate Body Report, ¶ 298.
[96] Appellate Body Report and Panel Report: Action by the Dispute Settlement Body, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/9 (May 1, 2012), *available at* http://trade.ec.europa.eu/doclib/docs/2013/january/tradoc_150280.pdf.
[97] Notification of an Appeal by the United States, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, *supra* note 95, ¶ 2; Appellate Body Report, ¶¶ 104–60, 298(a)(i).
[98] Appellate Body Report, ¶ 236.
[99] *Id.*
[100] *Id.* at ¶ 225.
[101] *Id.*
[102] *Id.*
[103] Statement by the United States at the May 24, 2012, Dispute Settlement Body Meeting, *available at* http://geneva.usmission.gov/2012/05/24/statement-by-the-united-states-at-the-may-24-2012-dsb-meeting/.
[104] *Id.*

[105] Agreement Under Article 21.3(b) of the DSU, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/10 (June 19, 2012), *available at* http://www.wtocenter.org.tw/SmartKMS/do/www/readDoc?document_id=123095.

[106] Statement by the United States at the July 23, 2013, Dispute Settlement Body Meeting, *available at* http://geneva.usmission.gov/wp-content/uploads/2013/07/July23-DSB.pdf.

[107] *Id*.

[108] Recourse to Article 22.2 of the DSU by Indonesia, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/12 (Aug. 13, 2013).

[109]Executive Summary of the Opening Statement of the United States of America, Recourse to Article 22.6 of the DSU by Indonesia, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, DS406 (Apr. 3, 2014), http://www.ustr.gov/sites/default/files/DS406.Oral_.Stmt_.ExecSummary.Fin_.pdf.

[110] Recourse to Article 22.6 of the DSU by the United States, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/14 (Sept. 2, 2013).

[111] Referring to Menthol in Cigarettes, Tobacco Products; Request for Comments, 78 Fed. Reg. 44484-01 (proposed July 24, 2013) (to be codified at 21 C.F.R. pt. 1140).

[112] Executive Summary of the Opening Statement of the U.S.A., at ¶ 1.

[113] Executive Summary of the Opening Statement of the U.S.A., at ¶ 10.

[114] Recourse to Article 22.2 of the DSU by Indonesia, Communication from the Arbitrator, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/16 (June 24, 2014).

[115] Appellate Body Report, ¶ 235.

[116] *Id.*at ¶ 236.