

# CRS Report for Congress

## Tobacco: Selected Legal Issues

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## Summary

Over the past decade, the courts and the Congress have been grappling with tobacco-related issues. Among these issues are the Food and Drug Administration's (FDA) attempt to regulate certain tobacco products under the Federal Food, Drug, and Cosmetic Act (FDCA); the Master Settlement Agreement (MSA) that resulted from lawsuits brought by states attorneys general against tobacco companies; federal, private party, and foreign lawsuits against tobacco companies; limits on tobacco advertising; and restrictions on selling and distributing tobacco to minors. During the 110th Congress, legislators have introduced several bills that address some of the above issues, including H.R. 1108, S. 625, S. 1162, and S.Con.Res. 21.

The FDCA gives the FDA authority to regulate food, drugs, devices, and cosmetics. In 1996, the FDA promulgated a final rule stating that, under the FDCA, it could regulate cigarettes and smokeless tobacco. In 2000, the U.S. Supreme Court, however, found that Congress had not given the FDA regulatory power over tobacco and overturned the final rule in *FDA v. Brown & Williamson Tobacco Corp.*

In the 1990s, states attorneys general brought lawsuits for reimbursement of their states' tobacco-related medical expenses. The states attorneys general and the tobacco companies reached a settlement in 1997, but this settlement never garnered the congressional approval needed for implementation. In 1998, however, 46 states, the District of Columbia, five U.S. territories, and the tobacco industry signed the MSA, worth \$206 billion over 26 years.

In 1999, the Clinton Administration filed a lawsuit against major tobacco companies and industry trade groups to recoup federal tobacco-related medical costs. In August 2006, the district court held that the tobacco companies violated two Racketeer Influenced and Corrupt Organization Act (RICO) claims and, among other remedies, ordered them to remove descriptors such as light, low tar, natural, mild, and ultra light from their packaging. The case is being appealed.

Since the U.S. Supreme Court's 1992 decision in *Cipollone v. Liggett Group Inc.*, individual and class action lawsuits have been brought against tobacco companies under theories such as fraudulent representation, conspiracy, breach of express warranty, and failure to warn. The private party suit section of this CRS report discusses the recent decision to certify as a class action the first light cigarettes case in a federal court, *Schwab v. Philip Morris U.S.A., Inc.*, as well as other selected state class actions. Suits brought in federal courts by foreign governments for medical care costs resulting from tobacco-related illnesses have not been successful.

Tobacco advertising is restricted at the federal, state, and local levels. The Federal Cigarette Labeling and Advertising Act (FCLAA), state laws and the MSA, and local ordinances limit tobacco advertising in ways such as prohibiting radio and television advertisements, compelling the use of health warning labels, banning the use of cartoons, and requiring individuals to have contact with a sales person before purchasing tobacco products. Additionally, federal law plays a role in enforcing laws that prohibit tobacco sales to minors.

## Contents

Introduction .....	1
The FDA's Ability to Regulate Tobacco Products .....	1
State Suits and the Master Settlement Agreement .....	5
The Federal Lawsuit .....	6
Private Party Suits .....	9
Foreign Suits in U.S. Federal Courts .....	12
Tobacco Advertising: Federal Regulations, MSA Restrictions, and Local Ordinances .....	13
Restrictions on Selling and Distributing Tobacco to Minors .....	16

# Tobacco: Selected Legal Issues

## Introduction

Over the past decade, the courts and the Congress have been grappling with tobacco-related issues. Among these issues are the Food and Drug Administration's attempt to regulate tobacco under the Federal Food, Drug, and Cosmetic Act; the Master Settlement Agreement that resulted from lawsuits by states attorneys general against tobacco companies; federal, private party, and foreign lawsuits against tobacco companies; limits on tobacco advertising; and restrictions on selling and distributing tobacco to minors. During the 110th Congress, legislators have introduced several bills that address some of the above issues, including H.R. 1108, S. 625, S. 1162, and S.Con.Res. 21.

## The FDA's Ability to Regulate Tobacco Products

Congress passed the Federal Food, Drug, and Cosmetic Act<sup>1</sup> (FDCA) in 1938 in response to a tragedy in which 100 people died after taking a drug containing a highly toxic substance. The statute increased the Food and Drug Administration's (FDA) enforcement power, gave the FDA jurisdiction over previously unregulated cosmetics and devices, and instituted safety measures such as requiring instruction labels on drugs and a pre-market approval process for new drugs.<sup>2</sup> The FDCA also "prohibited false therapeutic claims for drugs."<sup>3</sup> Since 1938, the law has been amended numerous times.<sup>4</sup> Under the FDCA, "drugs" fall into three categories or an inclusive fourth category comprised of articles intended to become a component of any of the other three categories. These three categories are (1) "articles recognized in the official United States Pharmacopoeia" or a similar standard-setting body for prescriptions and over-the-counter medications; (2) "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"; and (3) "articles (other than food) intended to affect the structure or any function of the body of man or other animals."<sup>5</sup> When determining whether an article is a drug under the second or third categories, the agency takes the intent of

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<sup>1</sup> 21 U.S.C. § 301 *et seq.*

<sup>2</sup> James T. O'Reilly, Food and Drug Administration, § 3.4 (2005).

<sup>3</sup> FDA's Role in Protecting and Promoting Public Health, available at [[http://www.fda.gov/centennial/centennial\\_files/textonly/index.html](http://www.fda.gov/centennial/centennial_files/textonly/index.html)].

<sup>4</sup> Amendments to the FDCA have included a broad range of topics such as food and color additives, animal drugs, drug abuse control, infant formula, saccharin labeling, orphan drugs, nutrition information and food allergen labeling, prescription drug marketing and importation, safe medical devices, and dietary supplements.

<sup>5</sup> 21 U.S.C. § 321(g)(1).

the vendor into account. However, even if a vendor does not intend to sell an item as a drug, the FDA can still govern it as a drug.<sup>6</sup> The term “drug” does not include food or dietary supplements.<sup>7</sup>

The FDCA defines “device” as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory . . . which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.<sup>8</sup>

In addition, in order to be a “device” under the FDCA, an item must fall within one of three categories that are nearly identical to those the FDCA uses to define a “drug” (see above). In classifying an item as a device, the FDA takes into account the manufacturer’s intent as to whether it is a device. This intent may be “indicated in the product’s labeling” and by how the manufacturer promotes, distributes, and sells the product.<sup>9</sup>

Combinations of drugs and devices are also regulated by the FDA. A drug-device combination product is defined to include, among other things, a product that contains a drug and a device that “are physically, chemically, or otherwise combined or mixed and produced as a single entity.”<sup>10</sup> Examples of this type of drug-device combination product include insulin injector pens, metered dose inhalers, transdermal patches, and catheters with antimicrobial coating.<sup>11</sup>

Under the theory that cigarettes and smokeless tobacco are “a combination of a drug, device, or biologic product,”<sup>12</sup> the FDA issued a final rule<sup>13</sup> in 1996 that would have given the agency jurisdiction over these tobacco products as drugs,

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<sup>6</sup> O’Reilly, § 13.3. Sunscreen is one example of such a product. *Id.*

<sup>7</sup> 21 U.S.C. § 321(g)(1)(D).

<sup>8</sup> 21 U.S.C. § 321(h).

<sup>9</sup> O’Reilly, § 18.2.

<sup>10</sup> 21 CFR § 3.2(e)(1).

<sup>11</sup> FDA, Frequently Asked Questions, [[http://www.fda.gov/oc/combination/faqs.html#\\_Toc88444656](http://www.fda.gov/oc/combination/faqs.html#_Toc88444656)].

<sup>12</sup> 21 U.S.C. § 353; FDCA § 503(g).

<sup>13</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 FR 44396 (1996). For a detailed description of the FDA’s 1996 final rule that would have restricted the sale of tobacco products, advertising, and labels, as well as the federal district and court of appeals cases leading up to the Supreme Court’s decision in *FDA v. Brown & Williamson Tobacco Corp.*, see CRS Report RL32619, *FDA Regulation of Tobacco Products: A Policy and Legal Analysis*, by C. Stephen Redhead and Vanessa Burrows.

devices, or both drugs and devices.<sup>14</sup> The agency’s rule concentrated on cigarettes and smokeless tobacco because the FDA did not have “sufficient evidence that [cigars] are drug delivery devices” and “because young people predominantly use cigarettes and smokeless tobacco products.”<sup>15</sup> The FDA found that nicotine was a drug under the above statutory definition providing that a drug is an article that “affect[s] the structure or any function of the body.”<sup>16</sup> This was because nicotine “causes addiction and other significant pharmacological effects on the human body.”<sup>17</sup> The FDA further concluded that cigarettes and smokeless tobacco have “device components that deliver nicotine to the body” and are “intended” by tobacco manufacturers to do so.<sup>18</sup> In the case of cigarettes, the FDA said that the device that delivers the drug nicotine has “components [that] work together upon combustion outside the body to form a nicotine-containing aerosol, which then delivers nicotine to the body when inhaled by the smoker.”<sup>19</sup> With smokeless tobacco, the device is a component that provides “nicotine to the consumer in a form that is palatable and absorbable by the buccal mucosa,” which is the lining inside the cheeks and lips.<sup>20</sup>

Implementation of the final rule would have enabled the FDA to regulate cigarettes and smokeless tobacco, including their access by minors, labeling, and advertising, under the “device” portion of the FDCA.<sup>21</sup> In order to reach tobacco advertising and youth access to these tobacco products, the FDA rule relied on the agency’s already-established authority to restrict the sale, use, and distribution of a potentially harmful device or a device that requires “collateral measures necessary for its use [if] the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.”<sup>22</sup> Under the FDA’s interpretation of the FDCA in the 1996 rule, the FDA could have issued rules on recordkeeping and manufacturing as well as reporting requirements in the event of contamination or

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<sup>14</sup> 61 FR 44400.

<sup>15</sup> 61 FR 44422 (quoting Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 FR 41314, 41322 (to be codified at 21 C.F.R. pts. 801, 803, 804, 897) (proposed August 11, 1995)).

<sup>16</sup> 21 U.S.C. § 321(g)(1).

<sup>17</sup> Annex to the Final Rule, Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 FR 44619, 44628-29 (1996).

<sup>18</sup> 61 FR 44628-29; 21 U.S.C. § 321(h).

<sup>19</sup> 61 FR 44649-50.

<sup>20</sup> 61 FR 44650.

<sup>21</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 FR 44396, 44400 (1996). The agency asserted that in order “to provide the most effective protection to the public health,” it had discretion in choosing whether to regulate combination products as drugs or devices, and it chose to regulate cigarettes and smokeless tobacco as devices. *Id.* at 44400.

<sup>22</sup> 21 U.S.C. § 360j(e); FDCA § 502(e).

“serious adverse events that are not well-known . . . in the scientific community.”<sup>23</sup> With the 1996 rule in place, the FDCA also would have allowed the FDA to place cigarettes in one of three classes of devices ranging from devices that present minimal harm to users to devices requiring FDA approval because of the risk for illness and the need for regulatory control. However, before the FDA could implement its final rule or issue any further regulations, the tobacco industry challenged the final rule. The industry argued that the FDCA did not permit the FDA to regulate tobacco, that the FDA could not regulate tobacco products because such items did not claim to provide health benefits, and that the FDA’s advertising restrictions violated commercial speech protections guaranteed by the First Amendment.

In *FDA v. Brown & Williamson Tobacco Corp.*, the U.S. Supreme Court held that the FDA did not have the statutory authority under the FDCA to regulate tobacco products as drug-delivery devices, and therefore did not reach the First Amendment issue.<sup>24</sup> The Court used the test it had articulated in *Chevron U.S.A., Inc. v. Natural Resources Defense Council*,<sup>25</sup> which addresses congressional intent and agency discretion:

When a court reviews an agency’s construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute . . . Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute.<sup>26</sup>

The Court found that Congress had spoken on the issue of the FDA’s authority to regulate tobacco products under the FDCA by passing laws — not administered by the FDA — that dealt with marketing, labeling, and education regarding tobacco products. Specifically, the Court held that the FDA’s interpretation of the FDCA, in its 1996 final rule, was contrary to Congress’s intent “expressed in the FDCA’s overall regulatory scheme and in tobacco-specific legislation that [Congress] has enacted.”<sup>27</sup> According to the Court, if the FDA had regulatory authority over tobacco under the FDCA, then tobacco companies could not market their products, and tobacco products would have to be banned because they are not safe or effective.<sup>28</sup>

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<sup>23</sup> 61 FR 44615-18.

<sup>24</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142-43 (2000).

<sup>25</sup> 467 U.S. 837 (1984).

<sup>26</sup> *Id.* at 842-43.

<sup>27</sup> *FDA*, 529 U.S. at 126.

<sup>28</sup> *Id.* at 135-37.

## State Suits and the Master Settlement Agreement<sup>29</sup>

Beginning in 1994, 41 states and Puerto Rico began filing lawsuits against tobacco companies for reimbursement of tobacco-related medical expenses, particularly Medicaid expenditures. These lawsuits eventually culminated in the 1998 Master Settlement Agreement (MSA), but initially they resulted in a June 1997 settlement between states attorneys general and tobacco manufacturers. The 1997 settlement incorporated all the provisions of the FDA's 1996 tobacco rule, discussed above. The 1997 proposal included changes to the FDCA and other federal statutes, and required congressional legislative action in order to take effect. The 1997 agreement, however, never took effect because Congress did not approve legislation implementing the settlement. Attempts by the 105th Congress to pass such legislation — comprised of the settlement and additional measures such as financial penalties if targets for reducing underage tobacco use were not met — ended when Senator John McCain's bill was defeated on two procedural votes on June 17, 1998, after an extended floor debate.<sup>30</sup> The negotiated agreement would have resulted in tobacco-related medical reimbursement payments to states of \$368.5 billion for 25 years and then \$15 billion per year after the first 25 years. Additionally, tobacco companies would have paid for programs to reduce adolescent tobacco use. This settlement would also have granted immunity to tobacco manufacturers from future lawsuits and ended existing class action lawsuits filed by smokers and their relatives, as well as nicotine addiction claims.

After the defeat of Senator McCain's bill, the major cigarette companies resumed contractual negotiations with the states to settle the lawsuits. In November 1998, attorneys general from 46 states, the District of Columbia, and five U.S. territories signed the MSA with the major tobacco companies. Four states — Mississippi, Florida, Texas, and Minnesota — did not join the MSA, but instead settled individually with the tobacco companies. The MSA did not settle individual, union, private health care, or class action suits. Through the MSA, states will receive annual payments of \$206 billion over 26 years. Each state needed to and did obtain its trial court's approval to receive the MSA funds. The MSA also prohibited certain advertising, marketing, and promotion of tobacco products (see the Tobacco Advertising section below).

Of the \$61 million paid to the states by tobacco companies to date, states have spent less than 8% on anti-smoking endeavors, according to a March 2007 article by the American Bar Association Journal.<sup>31</sup> Government Accountability Office figures indicate that states have spent even less on tobacco control, which it defines as efforts

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<sup>29</sup> For detailed explanations of the proposed 1997 National Tobacco Settlement and the 1998 Master Settlement Agreement, see CRS Report RL32619, *FDA Regulation of Tobacco Products: A Policy and Legal Analysis*, by C. Stephen Redhead and Vanessa Burrows.

<sup>30</sup> National Tobacco Policy and Youth Smoking Reduction Act, S. 1415, 105th Cong. (1998). See, e.g., 144 Cong. Rec. S5494-5511 (June 1, 1998); 144 Cong. Rec. S5737-62 (June 9, 1998); 144 Cong. Rec. S6275-89 (June 12, 1998).

<sup>31</sup> Mark Curriden, *Up in Smoke*, A.B.A. Journal, March 2007, at 27.



to include prevention, education, enforcement, and cessation services.<sup>32</sup> States have allocated 30% of their MSA payments to health care, including Medicaid, health insurance, and hospitals; 22.9% towards budget shortfalls; 7.1% to general purposes; 6% towards infrastructure; 5.5% to education; 5.4% to debt service on securitized funds; 3.5% on tobacco control; and 7.8% to other projects.<sup>33</sup> The states have not allocated 11.9% of their MSA payments.<sup>34</sup>

As noted, the MSA grew out of lawsuits by the states seeking reimbursement for their medical expenses on behalf of tobacco users. If a third party, such as a tobacco company, causes an illness or injury to someone, and a state provides medical care for that illness or injury, as, for example, out of Medicaid funds, then the state may sue the third party for reimbursement of such funds. Because the federal government pays for at least 50% of each state's Medicaid costs, by law the federal government is entitled to its share of any reimbursements of Medicaid funds that a state receives from a third party that caused an illness or injury on which Medicaid funds were expended.<sup>35</sup> With respect to the MSA, however, Congress enacted P.L. 106-31 (2000), which authorizes the states to keep reimbursements they receive from third parties.<sup>36</sup>

## The Federal Lawsuit

The federal lawsuit against major tobacco companies and industry trade groups began under the Clinton Administration in 1999 as a way for the U.S. government to recover tobacco-related medical costs paid by federal health care programs. The Department of Justice (DOJ) was seeking (1) restitution for money paid by the federal government's health care programs for treatment and care of persons with tobacco-related diseases, (2) a disgorgement of the profits that the tobacco industry allegedly earned by violating the Racketeer Influenced and Corrupt Organizations Act (RICO), and (3) orders preventing fraud and future violations of the law, such as racketeering or making false, deceptive, or misleading statements about cigarettes; as well as orders that the defendants take certain actions, such as issuing corrective statements, disclosing research, and funding smoking cessation programs.<sup>37</sup> In 2000, the U.S. District Court for the District of Columbia dismissed two claims by the government that would have provided for recovery under the Medical Care Recovery

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<sup>32</sup> Lisa Shames, Acting Director, Natural Resources and Environment, GAO, Testimony Before the Committee on Health, Education, Labor, and Pensions, U.S. Senate (February 27, 2007), *Tobacco Settlement: States' Allocations of Payments from Tobacco Companies for Fiscal Years 2000 through 2005*, at 14.

<sup>33</sup> Shames, *supra* note 32. Section 10908 of the Farm Security and Rural Investment Act of 2002 mandates that GAO report on "all programs and activities that States have carried out using funds received under all phases of the Master Settlement Agreement of 1997." P.L. 107-171.

<sup>34</sup> Shames, *supra* note 32.

<sup>35</sup> 42 U.S.C. § 1396b(d)(2)(B).

<sup>36</sup> FY1999 Emergency Supplemental Appropriations Act (P.L. 106-31), § 3031.

<sup>37</sup> *United States v. Philip Morris Inc.*, No. 99-2496, 1-2, 91-92 (D.D.C. filed February 2001) (DOJ First Amended Complaint).

Act as well as under the Medicare Secondary Payer Act provisions of the Social Security Act.<sup>38</sup> The suit then proceeded under two RICO claims, 18 U.S.C. § 1962(c) and (d).<sup>39</sup> Section 1962(c) criminalizes the association of persons, including corporations, with enterprises that conduct their affairs through “a pattern of racketeering activity,” which means that they commit two or more specified crimes within ten years. Section 1962(d) outlaws conspiracies to violate § 1962(c) or related provisions regarding racketeering activities. The government alleged that a pattern of racketeering activity existed because the defendants defrauded “individual smokers of their property (i.e., the money they spent on cigarettes).”<sup>40</sup>

During the trial, the defendants appealed the U.S. District Court for the District of Columbia’s opinion allowing the remedy of disgorgement — the giving up of the tobacco industry’s past profits gained by its deceptive practices — to the U.S. Court of Appeals for the D.C. Circuit. In 2005, the court of appeals overturned the district court’s opinion, thus limiting the remedial measures that the district court could impose if it found that the defendants had violated RICO.<sup>41</sup> Because the court of appeals allowed only forward-looking injunctive relief, the DOJ could not recover the \$280 billion disgorgement that had been sought for tobacco profits earned since 1971 for marketing to youth.<sup>42</sup> The court of appeals stated that injunctive relief under RICO<sup>43</sup> must focus on preventing future wrongdoing rather than on punishing past conduct. Noting that Congress explicitly crafted a set of remedial measures in the RICO statute and likely did not intend to provide other remedies, the court of appeals was “reluctant” to infer an additional remedy such as disgorgement.<sup>44</sup>

In August 2006, the U.S. District Court for the District of Columbia ruled that the defendants had violated RICO. The court found that the tobacco companies and trade industry organizations had conspired “to deceive the American public about the health effects of smoking and environmental tobacco smoke, the addictiveness of nicotine, the health benefits from low tar, ‘light’ cigarettes, and their manipulation of the design and composition of cigarettes in order to sustain nicotine addiction.”<sup>45</sup>

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<sup>38</sup> For a detailed explanation of the government’s claims under the Medical Care Recovery Act and the Medicare Secondary Payer Act, see CRS Report RS20091, *The Federal Lawsuit Against Tobacco Companies to Recover Health Care Costs*, by Henry Cohen. This report has been archived and is available from the author.

<sup>39</sup> For additional information on RICO, see CRS Report 96-950, *RICO: A Brief Sketch*, by Charles Doyle.

<sup>40</sup> *United States v. Philip Morris Inc., et al.*, No. 99-2496, 48 (D.D.C. 2000).

<sup>41</sup> *United States v. Philip Morris Inc.*, 396 F.3d 1190 (D.C. Cir. 2005), *cert. denied* 546 U.S. 960 (2005).

<sup>42</sup> Anthony J. Sebok, *The Federal Government’s RICO Suit Against Big Tobacco*, Findlaw.com, October 4, 2004, available at [<http://writ.lp.findlaw.com/sebok/20041004.html>].

<sup>43</sup> 18 U.S.C. § 1964(a).

<sup>44</sup> *Philip Morris*, 396 F.3d at 1200.

<sup>45</sup> *United States v. Philip Morris U.S.A., Inc.*, No. 99-2496, 1 (D.D.C. September 8, 2006) (continued...)

Although, as mentioned above, the U.S. Court of Appeals prevented the district court from imposing the remedy of disgorgement, the district court ordered the defendants to pay DOJ's legal costs, which totaled approximately \$1.93 million.<sup>46</sup> The district court also enjoined the defendants from using descriptors such as low tar, light, mild, and natural on their cigarette packaging and advertisements; ordered the defendants to place "onserts" or stickers with corrective statements on their packaging and to issue statements in newspapers and on television and retail displays; and extended the length of time that tobacco companies must make documents produced in litigation available to the public, a requirement that originated in the MSA.

Both the tobacco companies and the DOJ have filed notices of appeal with the U.S. Court of Appeals for the D.C. Circuit.<sup>47</sup> Neither of these notices states the parties' particular objections to the lower court decision, but rather enables the parties to appeal any and all parts of the judgment. In addition, pending the outcome of their appeal, the defendants moved to stay the district court's order banning them from using descriptors such as light or low tar. On September 28, 2006, the district court denied the defendants' request for a stay, concluding that "loss of market share, if it results from imposing an appropriate remedy to prevent and restrain past violations of the law, may well be the price Defendants have to pay for violations of RICO."<sup>48</sup> The defendants therefore filed a motion with the U.S. Court of Appeals for the D.C. Circuit requesting an emergency stay of the district court order pending appeal.<sup>49</sup> On October 31, 2006, the court of appeals granted the stay, enabling the tobacco companies to continue using descriptors such as ultra light or natural until the court rules on the appeal.<sup>50</sup>

On March 16, 2007, the U.S. District Court for the District of Columbia responded to a motion by certain defendants for clarification of the court's August 2006 order restricting the defendant's use of marketing descriptors such as natural and ultra lite. Noting that RICO provisions have effect outside the United States if the illegal activity abroad "causes a 'substantial effect' within the United States," the court concluded that the defendants were prohibited from using such marketing descriptors and express or implied health messages internationally as well as in the

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<sup>45</sup> (...continued)

(amended memorandum opinion).

<sup>46</sup> *United States v. Philip Morris U.S.A., Inc.*, No. 99-2496 (D.D.C. filed October 2, 2006) (bill of costs).

<sup>47</sup> *United States v. Philip Morris U.S.A., Inc.*, No. 99-2496 (D.D.C. September 11, 2006) (Philip Morris U.S.A. Inc., Altria Group, Inc., British American Tobacco Ltd., R.J. Reynolds Tobacco Co., Brown & Williamson Corp., and Lorillard Tobacco Co. Notices of Appeal); *United States v. Philip Morris U.S.A., Inc.*, No. 99-2496 (D.D.C. October 16, 2006) (DOJ Notice of Appeal).

<sup>48</sup> *United States v. Philip Morris U.S.A., Inc.*, No. 99-2496, 1 (D.D.C. September 28, 2006) (memorandum opinion on stay appeal).

<sup>49</sup> *United States v. Philip Morris U.S.A., Inc.*, Nos. 06-5267 - 06-5272 (D.C. Cir. October 2, 2006) (defendants' emergency motion to stay the judgment).

<sup>50</sup> *Appeals Court Puts Ruling Against Big Tobacco on Hold*, Wash. Post, November 1, 2006, at A9.

United States.<sup>51</sup> Several countries, including Australia, Brazil, and European Union members, currently prohibit marketing descriptors such as light and low-tar.<sup>52</sup> The district court order banning the use of marketing descriptors domestically and internationally will not take effect immediately because of the appellate court's stay of the district court order and the pending appeal. Defendants Philip Morris U.S.A., Inc., Altria, R.J. Reynolds, Brown & Williamson, Lorillard, and BATCo. may be affected in differing degrees by the international application of the order due to the level of their international sales.

## Private Party Suits

Prior to 1992, tobacco lawsuits were typically individual product liability and negligence suits brought by smokers or their relatives seeking damages for smoking-related illnesses. The tobacco industry generally prevailed in these cases by arguing that the Federal Cigarette Labeling and Advertising Act (FCLAA),<sup>53</sup> which required warning labels, preempted plaintiffs' claims that the tobacco companies had a duty to warn consumers.<sup>54</sup> In some cases, however, tobacco manufacturers prevailed by arguing that smokers assumed the risks of smoking.<sup>55</sup> Then, in 1992, in *Cipollone v. Liggett Group, Inc.*, the U.S. Supreme Court made it more feasible for smokers to recover. Although the Court held that federal laws requiring warning labels<sup>56</sup> precluded states from imposing additional requirements on cigarette advertising and labeling, and therefore precluded lawsuits alleging that the federally required warning labels were inadequate, the Court stated that federal law did not preclude "state-law damages actions." Examples of state-law damages actions include failure-to-warn lawsuits based on tobacco companies' "testing or research practices or other actions unrelated to advertising or promotion," or claims of breach of express warranty, fraudulent representation, and conspiracy.<sup>57</sup>

This section now examines selected recent suits brought by private parties after *Cipollone*. In addition to the class action and individual suits discussed below, tobacco companies have been sued by their own shareholders for decreased stock prices due to deceptive practices, and by insurance companies for medical expenses resulting from fraud, conspiracy, racketeering, misrepresentation, and antitrust violations.

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<sup>51</sup> *United States v. Philip Morris U.S.A., Inc.*, No. 99-2496, 6, 8 (D.D.C. March 16, 2007) (memorandum opinion accompanying Order #1028).

<sup>52</sup> *Judge Extends 'Light' Cigarette Ban Overseas*, CNNMoney.com, March 16, 2007.

<sup>53</sup> 15 U.S.C. § 1331-41.

<sup>54</sup> *See, e.g.*, *Pennington v. Vistrion Corp.*, 876 F.2d 414 (5th Cir. 1989); *Forster v. R.J. Reynolds Tobacco Co.*, 437 N.W.2d 655, 660 (Minn. 1989).

<sup>55</sup> *See* Brief for Petitioner at 13-14, n.3, *Philip Morris U.S.A., Inc. v. Williams*, 549 U.S. \_\_\_ (filed July 2006) (No. 05-1256) (and cases cited therein).

<sup>56</sup> 15 U.S.C. §§ 1331-41, 4402.

<sup>57</sup> *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 520, 524-25, 530-31 (1992).

Long-term Marlboro smokers filed a class action suit, *Caronia v. Philip Morris U.S.A., Inc.*, seeking to have the manufacturer provide low dose CT scans for lung cancer on an annual basis or more frequently if the scan shows signs of cancer.<sup>58</sup> The plaintiffs allege that Philip Morris’s “wrongful design, manufacturing, and marketing” places them at a higher risk for lung cancer.<sup>59</sup> Philip Morris expects the court to dismiss the case because “most states don’t recognize medical monitoring as a remedy or cause of action.”<sup>60</sup> Previous lawsuits asking for medical monitoring as relief have not been successful.<sup>61</sup> Additionally, the utility of CT scans for lung cancer is a subject of debate.<sup>62</sup>

In the federal class action lawsuit *Schwab v. Philip Morris U.S.A., Inc.*, lead plaintiff Barbara Schwab sued six tobacco companies in the U.S. District Court for the Eastern District of New York, alleging that the tobacco industry committed fraud and misled customers by marketing light cigarettes as less dangerous than regular cigarettes.<sup>63</sup> On September 25, 2006, the *Schwab* case became the first light cigarettes, or “lights,” case to receive class certification from any federal court. The class includes individuals who purchased light cigarettes since the first light cigarette was introduced in 1971. The class could be extended to include individuals who bought low-tar cigarettes.<sup>64</sup> The court found that the MSA does not preclude the suit because, in the MSA, the states, not individual smokers, were compensated. On October 6, 2006, the defendants asked the U.S. Court of Appeals for the Second Circuit to review the federal district court’s decision to certify the class action lawsuit and sought a stay pending review.

In most states, courts reportedly have denied class action status to plaintiffs for private lawsuits against tobacco companies.<sup>65</sup> However, in Florida, class action status was granted by the Circuit Court of Miami-Dade County in *Engle v. Liggett Group*, a case against tobacco companies and industry trade groups in which a jury awarded \$145 billion in punitive damages. After the jury verdict, however, the class

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<sup>58</sup> *Caronia v. Philip Morris U.S.A., Inc.*, No. 06-224 (E.D.N.Y. January 19, 2006).

<sup>59</sup> Sean Wajert, *Medical Monitoring Claim Pursued in New York State*, Washington Legal Foundation Legal Opinion Letter, Vol. 16, No. 15 (June 2, 2006).

<sup>60</sup> Peter Geier, *Smokers Sue Tobacco Company for Lung Scans*, Nat’l L. J., November 21, 2006.

<sup>61</sup> *Id.*

<sup>62</sup> Gina Kolata, *Researchers Dispute Benefits of CT Scans for Lung Cancer*, N.Y. Times, March 7, 2007.

<sup>63</sup> *Schwab v. Philip Morris U.S.A., Inc.*, No. 04-CV-1945 (E.D.N.Y. September 25, 2006) (memorandum and order), available at [<http://www.nyed.uscourts.gov/pub/rulings/cv/2004/04cv1945mo.pdf>]. The defendant tobacco companies in the *Schwab* case are R.J. Reynolds Tobacco Co., Brown & Williamson Tobacco Corp., British American Tobacco Ltd., Lorillard Tobacco Co., Liggett Group Inc., and Philip Morris U.S.A., Inc.

<sup>64</sup> *Id.* at 540.

<sup>65</sup> Anthony Sebok, *The Federal Government’s RICO Suit Against Big Tobacco*, Findlaw.com, October 4, 2004, available at [<http://writ.lp.findlaw.com/sebok/20041004.html>].

of up to 700,000 Florida smokers was de-certified by Florida's Third District Court of Appeal.<sup>66</sup> On July 6, 2006, the Florida Supreme Court upheld the decision to de-certify the class.<sup>67</sup> The court stated that causation and the proportion of the defendants' fault was too individualized to be litigated as a class action suit.<sup>68</sup> To maintain a class action suit, the issues that the plaintiffs have in common must predominate over the individual plaintiffs' issues. In this case, the Florida Supreme Court found, individual plaintiffs' issues predominated. Such issues included whether cigarettes, or some other factor, caused the plaintiff's illness, and the percentage of fault that should be attributed to each defendant tobacco company if a plaintiff smoked multiple brands. The court did uphold smaller individual damage awards of \$2,850,000 and \$4,023,000 for two Florida cancer patients.

The Florida Supreme Court decision did not prevent individual smokers (or families of deceased smokers) from filing individual lawsuits instead of a class action. The court upheld most of the jury's findings that cigarettes are addictive, defective, and unreasonably dangerous products that cause diseases.<sup>69</sup> This aspect of the court's decision gives plaintiffs an advantage in any individual lawsuits they may file because the individuals will not have to prove these findings again — that cigarettes are addictive, defective, and unreasonably dangerous. A jury awarded \$37.5 million for medical expenses, pain and suffering, and loss of consortium to Yolanda Lukacs. She was the widow of former *Engle* class action member John Lukacs, who sued cigarette manufacturers in an individual suit that was allowed due to his terminal condition. However, the court has not entered a final judgment in the Lukacs case or ordered a trial for punitive damages, as the defendants are awaiting a decision from the U.S. Supreme Court granting or denying certiorari in the *Engle* case.<sup>70</sup>

On December 15, 2005, the Supreme Court of Illinois overturned a verdict of \$7.1 billion in compensatory damages and \$3 billion in punitive damages in the consumer-fraud and deceptive trade practices class action of *Price v. Philip Morris U.S.A., Inc.*<sup>71</sup> An Illinois circuit court had certified a class that consisted of 1.14 million plaintiffs who bought Cambridge Lights and Marlboro Lights in Illinois from the time that the cigarettes were first placed on the market until February 2001. The plaintiffs in *Price* alleged that tobacco companies committed fraud by advertising light cigarettes as having lower tar and nicotine levels and leading consumers to think that such cigarettes were safer to smoke than full flavor cigarettes.<sup>72</sup> The court held

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<sup>66</sup> *Liggett Group, Inc. v. Engle*, 853 So. 2d 434 (Fla. Dist. Ct. App. 2003).

<sup>67</sup> *Engle v. Liggett Group, Inc.*, 2006 Fla. LEXIS 1480; 31 Fla. L. Weekly S 464 (Fla. 2006).

<sup>68</sup> *Engle*, 2006 Fla. LEXIS 1480, at \*5.

<sup>69</sup> *Id.* at \*7-\*8.

<sup>70</sup> Forrest Norman, *Lawyers for Tobacco Plaintiff Want \$37.5 Million Judgment OK'd*, Daily Bus. Rev., March 16, 2007.

<sup>71</sup> 2005 Ill. LEXIS 2071 (Ill. 2005). The Illinois Supreme Court denied the class's motion for rehearing on May 5, 2006.

<sup>72</sup> Melanie Warner, *Big Award on Tobacco is Rejected by Court*, N.Y. Times, July 7, 2006, (continued...)

that the Federal Trade Commission had authorized light and low-tar labeling and therefore that Philip Morris U.S.A., Inc. could not be held liable as long as the company complied with Federal Trade Commission requirements, even if the terms were false or misleading. The U.S. Supreme Court denied certiorari on November 27, 2006, thus allowing the ruling of the Illinois Supreme Court to stand.

In August 2002, the California Supreme Court enabled individuals to sue tobacco companies by holding that a statute<sup>73</sup> granting tobacco manufacturers immunity from products liability suits applied only from the date of the statute's enactment on January 1, 1988, until the statute's repeal effective January 1, 1998. The court found that general tort principles applied to conduct before and after the ten-year immunity period.<sup>74</sup> In a separate case decided on the same day, the court also found that the immunity statute did not prohibit lawsuits alleging that tobacco additives create an unreasonably dangerous product “that exposed smokers to dangers beyond those commonly known to be associated with cigarette smoking.”<sup>75</sup> In a more recent ruling, *Grisham v. Philip Morris*, the California Supreme Court held that the state's two year statute of limitations for filing a physical injury claim starts to run after a “smoker is diagnosed with a disease caused by the cigarettes.”<sup>76</sup> The ruling did not address whether the statute of limitations would have run if an individual was diagnosed with more than one illness, “[f]or example, if a smoker were diagnosed with emphysema five years ago and then lung cancer last month — but only files suit after the lung cancer diagnosis — the statute of limitations may have run.”<sup>77</sup> Defendant tobacco companies had argued that the statute of limitations should begin when smokers discover they are addicted to cigarettes.<sup>78</sup>

## Foreign Suits in U.S. Federal Courts

The Governments of Guatemala, Nicaragua, and Ukraine sued major American tobacco companies in the U.S. District Court for the District of Columbia for money they had spent on medical care for their citizens' tobacco-related illnesses. The Government of Guatemala alleged that the tobacco companies misrepresented the dangers of cigarette smoking, and as a result, the Guatemalan government waited before making efforts to shrink its smoking population.<sup>79</sup> Reasoning that “the injury

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<sup>72</sup> (...continued)  
at C1.

<sup>73</sup> Cal. Civ. Code § 1714.45, *repealed* by 1997 Cal. Stat. ch. 570, § 1.

<sup>74</sup> *Myers v. Philip Morris Cos., Inc.*, 28 Cal. 4th 828 (Cal. 2002).

<sup>75</sup> *Naegele v. R.J. Reynolds Tobacco Co.*, 28 Cal. 4th 856 (Cal. 2002).

<sup>76</sup> Millie Lapidario, *Tobacco Claims Will Start Smoking Again, Thanks to Calif. Ruling*, The Recorder, February 20, 2007.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> Sandra Torry, *Cigarette Firms Sued by Foreign Governments*, Wash. Post, January 17, 1999, at A12.

that [the nations] purportedly suffered occurred only as a consequence of the harm to individual smokers,” the district court dismissed the lawsuit.<sup>80</sup>

The U.S. Court of Appeals for the D.C. Circuit affirmed the dismissal, noting that it concurred with seven circuits “that the alleged injuries of the third-party payors are too remote to have been proximately caused by the defendants’ alleged conduct.”<sup>81</sup> The court also held that the foreign governments did not have standing “unless there is a clear indication by the Supreme Court or one of the two coordinate branches of government to grant such standing” to foreign nations to sue in the U.S. on behalf of their foreign citizens.<sup>82</sup> The foreign governments had argued that they were suing on behalf of their people and were “seeking to protect their governments’ treasuries.”<sup>83</sup> On October 29, 2001, the U.S. Supreme Court denied certiorari, which allowed the court of appeals decision to stand.

## **Tobacco Advertising: Federal Regulations, MSA Restrictions, and Local Ordinances<sup>84</sup>**

The Federal Cigarette Labeling and Advertising Act (FCLAA) limits advertising of tobacco products.<sup>85</sup> The act prevents advertising of cigarettes, little cigars, and smokeless tobacco via electronic communications under the jurisdiction of the Federal Communication Commission, such as radio and wire communications, as well as broadcast, satellite, and cable television. In combination with other federal statutes, the act requires health warning labels on cigarette and smokeless tobacco packaging, as well as on all cigarette and most smokeless tobacco advertisements.<sup>86</sup> The health warnings must be rotated several times per year according to a manufacturer-submitted plan approved by the Federal Trade Commission.<sup>87</sup> Cigars are not subjected to similar advertising and warning restrictions. Because of the FCLAA’s preemption provision, states cannot impose their own health warning labels on cigarettes.<sup>88</sup>

The FCLAA’s preemption provisions do not apply to the MSA because the states and tobacco manufacturers voluntarily agreed to waive “any and all claims that

<sup>80</sup> *Guatemala v. Tobacco Inst., Inc.*, 83 F. Supp. 2d 125, 129 (D.D.C. 1999).

<sup>81</sup> *Guatemala v. Tobacco Inst., Inc.*, 249 F. 3d 1068, 1069 (D.C. Cir. 2001), *cert. denied*, 534 U.S. 994 (2001).

<sup>82</sup> *Id.* at 1073.

<sup>83</sup> *See id.* at 1072.

<sup>84</sup> For information on federal advertising laws related to alcohol, tobacco, mail (including junk mail), telephone, commercial email (spam), and the Federal Trade Commission Act, see CRS Report RL32177, *Federal Advertising Law: An Overview*, by Henry Cohen.

<sup>85</sup> 15 U.S.C. § 1331-41.

<sup>86</sup> 15 U.S.C. §§ 1331-41, 4402. Federal law does not require warning labels on outdoor billboards that advertise smokeless tobacco. 15 U.S.C. § 4402(a)(2).

<sup>87</sup> 15 U.S.C. §§ 1333(c)(1), 4402(c).

<sup>88</sup> 15 U.S.C. § 1334(b); *Cipollone v. Liggett Group Inc.*, 505 U.S. 504 (1992).



the provisions of this Agreement violate the state or federal constitutions.”<sup>89</sup> The MSA restricted tobacco advertising in several ways, although it did not restrict certain forms of advertising, such as print and online advertisements or marketing inside retail locations.<sup>90</sup> The MSA banned cartoons; tobacco advertising on public transportation; sponsorship of certain team and league sports; stadium naming rights; gifts to minors of non-tobacco merchandise in exchange for proofs of purchase of tobacco products; free samples of tobacco products in places other than adult-only facilities; signs outside stores larger than 14 square feet; and billboards in arenas, stadiums, malls, and arcades. However, the MSA allows advertisements that are located within and not visible outside of adult-only facilities.<sup>91</sup> Within MSA limitations, tobacco companies may still sponsor certain musical, sporting, and cultural events. The MSA also bans the sale and distribution of merchandise with tobacco product brand names, except for at brand-name sponsored events. The MSA prohibits payments to the media for the promotion, mention, or use of tobacco products, except for adult-only media. Moreover, the MSA prohibits tobacco companies from targeting or promoting tobacco to minors.<sup>92</sup>

Though states attorneys general signed and trial courts ratified the MSA, several states and cities created additional restrictions on tobacco advertising. For example, Baltimore passed ordinances prohibiting tobacco and alcohol advertisements on billboards, except for commercial and industrial zones of the city. The U.S. Court of Appeals for the Fourth Circuit upheld Baltimore’s ordinances in two cases,<sup>93</sup> finding that they do not violate the First Amendment.<sup>94</sup>

In 1999, the Massachusetts Attorney General promulgated advertising restrictions — on cigarettes, smokeless tobacco, little cigars, and cigars — that he intended to fill the gaps left by the MSA. The regulations prohibited all sizes of outdoor tobacco advertisements within 1,000 feet of playgrounds, schools, and parks, including advertisements located within a store that were visible from the outside of that store. The rules also imposed a similar 1,000-foot state ban on point-of-sale retail displays if the displays were less than five feet tall and located in stores

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<sup>89</sup> Master Settlement Agreement, p. 99, available at [[http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/1109185724\\_1032468605\\_cigmsa.pdf](http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/1109185724_1032468605_cigmsa.pdf)].

<sup>90</sup> Since the 1998 MSA, the tobacco industry has increased its spending on marketing in ways that comply with the MSA, such as paying “bonuses to retailers who meet sales targets and post in-store signs.” Tobacco manufacturers also offer “direct-mail coupons good for a free pack for each purchase of two.” Myron Levin, *Tobacco Deal Yet to Clear the Air*, LA Times, November 27, 2003.

<sup>91</sup> Master Settlement Agreement, p. 18.

<sup>92</sup> *Id.* at 14-21.

<sup>93</sup> *Penn Advertising of Baltimore, Inc. v. Schmoke*, 101 F.3d 332 (4th Cir. 1996), *cert. denied*, 520 U.S. 1204 (1997); *Anheuser-Busch v. Schmoke*, 101 F.3d 325 (4th Cir. 1996), *cert. denied*, 520 U.S. 1204 (1997).

<sup>94</sup> For further information on First Amendment issues raised by advertising laws, see CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by Henry Cohen.

accessible to youth.<sup>95</sup> Additionally, the attorney general restricted tobacco promotions, samples, and cigar labels; banned self-service displays; and required customers to have contact with a sales person before handling or purchasing tobacco products.<sup>96</sup> In 2001, however, the U.S. Supreme Court held in *Lorillard Tobacco Co. v. Reilly* that the FCLAA preempted Massachusetts' outdoor advertising and point-of-sale restrictions for cigarettes, because the FCLAA preempts state regulations of cigarette advertising and promotion.<sup>97</sup> Therefore, the Court struck down that portion of the regulations. The Court noted, however, that the FCLAA preemption provisions do not apply to smokeless tobacco or cigars, or restrictions on cigarette sales.<sup>98</sup>

Therefore, the Court had to reach the issue of whether Massachusetts' outdoor and point-of-sale advertising regulations violated the First Amendment, which guarantees freedom of speech.<sup>99</sup> Though Massachusetts had a compelling interest in protecting youth from tobacco products, the Court found that the restrictions on outdoor advertising of cigars and smokeless tobacco were overbroad in that they prohibited advertising "in a substantial portion of the major metropolitan areas of Massachusetts," included oral communications, and imposed burdens on retailers with limited advertising budgets.<sup>100</sup> The Court also upheld challenges by smokeless tobacco and cigar companies to the outdoor advertising restrictions on the grounds that adults have a right to information and the tobacco industry has a right to communicate truthful speech on legal products.<sup>101</sup> The Justices then struck down the similar 1,000-foot state ban on point-of-sale retail displays for cigars and smokeless tobacco under five feet tall in stores accessible to youth. They noted that the prohibition did not advance the goal of preventing minors from using tobacco products because some children are taller than five feet and others can look up at their surroundings.<sup>102</sup> According to one source, at least 20 state and local laws have been repealed as a result of *Lorillard*.<sup>103</sup>

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<sup>95</sup> Mass. Regs. Code tit. 940, §§ 21.04, 22.06.

<sup>96</sup> *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 534-36 (2001).

<sup>97</sup> *Id.* at 551-52.

<sup>98</sup> *Id.* at 553.

<sup>99</sup> The First Amendment applies to advertising, but the U.S. Supreme Court has held that it "affords a lesser protection to commercial speech than to other constitutionally guaranteed expression" and analyzes commercial speech differently from other forms of expression. *United States v. Edge Broadcasting Co.*, 509 U.S. 418, 426 (1993); *see* *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980) (four-part test for commercial speech analysis).

<sup>100</sup> *Lorillard*, 533 U.S. at 562, 564-65.

<sup>101</sup> *Id.* at 564. Additionally, the Court reasoned that the attorney general's restriction on in-store advertising that can be viewed from the outside "presents problems in establishments like convenience stores, which have unique security concerns." *Id.* at 565.

<sup>102</sup> *Id.* at 566.

<sup>103</sup> David L. Hudson Jr., *Tobacco Ads*, Speech topic - Advertising & First Amendment, [http://www.firstamendmentcenter.org/speech/advertising/topic.aspx?topic=tobacco\_alc

Finally, as to the question of Massachusetts’s regulation of cigarette, smokeless tobacco, and cigar sales, the cigarette petitioners did not argue that the FCLAA preempted Massachusetts law.<sup>104</sup> As a result, the Court evaluated arguments from cigarette, smokeless tobacco, and cigar petitioners that certain sales restrictions violated the First Amendment. The Court upheld restrictions banning self-service displays and requiring customers to have contact with a sales person before handling or purchasing tobacco products.<sup>105</sup> According to the Justices, the state had a substantial interest in preventing minors from accessing tobacco products, and the regulation was narrowly tailored so as not to significantly affect adult access to tobacco products.<sup>106</sup>

## Restrictions on Selling and Distributing Tobacco to Minors

All 50 states ban tobacco sales to individuals under age 18, and federal law plays a role in this restriction.<sup>107</sup> The Public Health Service Act authorizes the Secretary of Health and Human Services (HHS) to “make an allotment each fiscal year for each state” to be used for “activities to prevent and treat substance abuse.”<sup>108</sup> Under a 1992 amendment to this statute, sponsored by Representative Michael Synar and known as the “Synar Amendment,” the Secretary may make such grants “only if the State has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute such product to any individual under the age of 18.”<sup>109</sup>

Under the Synar Amendment, states must enforce their bans through annual random, unannounced inspections.<sup>110</sup> If a state fails to comply with the federal enforcement provisions and reporting requirements on its enforcement activities, the federal government may reduce that state’s federal funding for substance abuse treatment.<sup>111</sup> According to the HHS regulations, the goal of the Synar Amendment’s random inspections requirement is to achieve 80% or higher compliance with laws prohibiting tobacco sales and the distribution of tobacco products to individuals under 18.<sup>112</sup>

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<sup>103</sup> (...continued)  
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<sup>104</sup> *Lorillard*, 533 U.S. at 566.

<sup>105</sup> *Id.* at 567.

<sup>106</sup> *Id.* at 569.

<sup>107</sup> Barnaby J. Feder, *U.S. Imposes Rules on Tobacco Sales to Minors*, NY Times, January 19, 1996.

<sup>108</sup> 42 U.S.C. § 300x-21.

<sup>109</sup> 42 U.S.C. § 300x-26(a)(1). The Synar Amendment was enacted as § 1926 of the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, P.L. 102-321 (1992).

<sup>110</sup> 42 U.S.C. § 300x-26(b)(2)(A).

<sup>111</sup> *Id.* at § 300x-26(c).

<sup>112</sup> 45 C.F.R. § 96-130(g).