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MEASURES TO CONTROL TOBACCO USE: IMMUNITY, ADVERTISING RESTRICTIONS, AND FDA CONTROL AS PROPOSED IN THE FAILED TOBACCO SETTLEMENT

INTRODUCTION

Tobacco use is one of the most serious threats to the public health facing the United States today. The United States Department of Health and Human Services (DHHS) estimates that 400,000 people die each year from tobacco-related illnesses. In fact, tobacco use alone claims more lives than AIDS, car accidents, alcohol, homicides, illegal drugs, and suicides combined. It is the single leading cause of preventable death in this country. As a result, measures to curb the use of tobacco continue to be an issue in congressional debates and on the front pages of major newspapers.

Beginning in June of 1997, the tobacco industry (Industry) and Congress attempted to create a scheme of regulations designed to control tobacco use. These negotiations began after many states instituted lawsuits against the Industry in an attempt to recover the Medicaid payments that had been used to provide medical treatment to people suffering from tobacco-induced diseases. On November 7, 1997, Senator John McCain (R - Arizona) introduced a bill in the Senate, entitled the "Universal Tobacco Settlement Act," outlining the terms of a proposed settlement. Yet, the bill was never enacted into law. On April 8, 1998, amid great strife and disagreement, the Industry withdrew from further

2. See DHHS Public Health Service, Cigarette Smoking-Related Mortality, OFFICE ON SMOKING AND HEALTH 1, 1 (1995) (reporting that "[e]very year smoking kills more than 276,000 men and 142,000 women").
5. See discussion infra Part II.D.1.
Not only did the Industry abandon the tobacco settlement, it also vowed to challenge any future bills proposed by Congress. Members of Congress, however, promise to continue the crusade for tobacco legislation.

This Comment focuses on some important measures the failed tobacco settlement (Failed Settlement) would have implemented and the role they could play in controlling the use of tobacco. Regardless of whether Congress continues negotiations with the tobacco industry in the future, each measure analyzed in this Comment is deserving of attention. Each measure could have significant repercussions on the tobacco industry as well as on the way in which tobacco products are manufactured and distributed. Part I examines current federal legislation's attempt to restrict tobacco sale and use. Part II explores the option of granting the Industry immunity from the mounting litigation against it in order to encourage another settlement proposal in the future. The history of prior lawsuits brought against tobacco manufacturers will be examined and juxtaposed against the current wave of lawsuits facing the Industry. Part III discusses attempts at controlling tobacco use through restrictions on advertising. This part will analyze the constitutionality of the restrictions on advertising that would have been enacted through the Failed Settlement. The analysis will include an historical exploration on the development of commercial speech as protected by the First Amendment, as well as a discussion of whether any advertising restriction could pass First Amendment scrutiny. Part IV examines whether allowing the Food & Drug Administration (FDA or the Agency) the authority to regulate the manufacturing and distribution of tobacco products is a viable option. It will include discussion of how the FDA, for years, refused to assert jurisdiction over tobacco products and its recent attempt to control the Industry by classifying tobacco products as drug-devices. Finally, Part V is devoted to a summation of each proposition explored. The discussion will include a conclusion of which measure will serve best the interest of controlling tobacco, and why other measures will be ineffective or improper.

8. See id.
9. See id.
I. FEDERAL REGULATION OF CIGARETTES AND SMOKELESS TOBACCO PRODUCTS

A. Regulation of Cigarettes

In a 1954 public report, the Surgeon General found that smoking cigarettes increased the likelihood of death and disease. Soon after the Surgeon General’s report, Congress began developing a comprehensive plan to handle cigarette labeling and advertising. As a result, the Federal Cigarette Labeling and Advertising Act was enacted in 1965 (FCLAA or the Act) to both inform the public of any adverse health effects associated with tobacco use and protect the tobacco manufacturers from suffering any significant business losses. The Act requires several specific health warnings on cigarette packaging and advertising, informing consumers that tobacco products may expose them to certain health risks. The warnings must be conspicuous to the public, and the

10. See UNITED STATES DEP’T OF HEALTH, EDUC. & WELFARE, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 28-29 (1964) (comparing the mortality ratios of cigarette smokers and non-smokers). The likelihood of cigarette smokers dying from coronary artery disease is seventy percent higher than those who do not smoke. See id. at 29. The likelihood of cigarette smokers developing and dying from chronic bronchitis and emphysema is five-hundred percent higher than those who do not smoke. See id. The likelihood of smokers dying from lung cancer is one-thousand percent higher than for those who do not smoke. See id.

11. See 15 U.S.C. § 1331 (1994) (“[I]t is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health.”).

12. See 15 U.S.C. § 1331 (1994) (stating that it is the policy of Congress to establish a program whereby “the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package . . . and in each advertisement” while at the same time “commerce and the national economy may be (A) protected . . . and (B) not impeded . . .”

13. See id. at §§ 1333 (a)(1)-(2), (b)(1)-(2). All cigarette packing and advertising, other than advertising that appears on outdoor billboards, must contain one of the following four labels in conspicuous and legible type:

SURGEON GENERAL’S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL’S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks To Your Health.

SURGEON GENERAL’S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low
manufacturers are required to rotate each warning to ensure that the same warning is not used on all the packaging.\textsuperscript{14}

When the Act was passed in 1965, tobacco manufacturers were required to warn consumers that smoking was \textit{hazardous} to their health. Subsequent amendments to the Act in 1970 substituted the original warning to indicate that smoking is \textit{dangerous} to health.\textsuperscript{15} Amendments in 1984 required additional warnings on packaging and advertising. In addition to the mandated warning labels, the Act also preempted the states and federal agencies from imposing more stringent health warning requirements.\textsuperscript{16} No other state or federal agency may require cigarette packaging or advertising to carry any other warning except those required by the Act.\textsuperscript{17}

In 1967, the Federal Communications Commission (FCC) required that all television and radio broadcasters provide equal time on their airwaves to warn the public about the dangers of cigarette smoking.\textsuperscript{18} In other words, for every minute of pro-tobacco advertising, there would be one minute devoted to informing viewers of the dangers of tobacco use. As an administrative agency, the FCC could implement the restriction under its authority to control television broadcast. Over 1,000 anti-tobacco warnings were aired by the major television networks as a result of the FCC’s rule.\textsuperscript{19}

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\textbf{Birth Weight.}

\textbf{SURGEON GENERAL’S WARNING:} Cigarette Smoke Contains Carbon Monoxide.

\textit{Id.} Advertising on outdoor billboards are required to carry one of the four following warnings enclosed in a black border:

\textbf{SURGEON GENERAL’S WARNING:} Smoking Causes Lung Cancer, Heart Disease, And Emphysema.

\textbf{SURGEON GENERAL’S WARNING:} Quitting Smoking Now Greatly Reduces Serious Health Risks.

\textbf{SURGEON GENERAL’S WARNING:} Pregnant Women Who Smoke Risk Fetal Injury, And Premature Birth.

\textbf{SURGEON GENERAL’S WARNING:} Cigarette Smoke Contains Carbon Monoxide.

\textit{Id.} §§ 1333 (a)(3), (b)(3).

\textsuperscript{14} \textit{See id.} § 1333 (b), (c).

\textsuperscript{15} \textit{See id.} § 1333 (citing Pub. L. 91-222, which substituted ‘‘Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health’ for ‘Caution: Cigarette Smoking May Be Hazardous to Your Health.’’).\textsuperscript{16} \textit{See id.} § 1334.

\textsuperscript{17} \textit{See id.}

\textsuperscript{18} \textit{See} \textsc{Peter D. Jacobson & Jeffrey Wasser\-man, Tobacco Control Laws: Implementation and Enforcement} 6 (1997).

\textsuperscript{19} \textit{See id.}
In 1969, however, Congress stripped the FCC of its power to implement restrictions on tobacco advertising by passing the Public Health Cigarette Smoking Act of 1969 (Act of 1969). The Act of 1969 banned all cigarette advertising on television and radio, irrespective of whether the message encouraged or discouraged tobacco use. Ironically, when the Act of 1969 was enacted, it brought relief to the tobacco industry. The tobacco industry feared that the public warnings heightened consumer awareness of the perils of smoking, which would lead to greater regulation of tobacco. Because it is unlawful to advertise on any medium controlled by the FCC, future restrictions that would exacerbate awareness of the dangers of cigarette smoking were curtailed.

In order for Congress to fulfill its policy of warning the public about the dangers of smoking while maintaining the national economy, it directed the Secretary of Health and Human Services (Secretary) to provide Congress a report each year on the current health consequences of smoking. Under this directive, the Secretary was empowered with the authority to make recommendations on whatever legislation deemed appropriate to educate the public.

After passing the Act of 1969, additional legislation was not implemented until thirteen years later. Congress decided, at that time, that information about the addictive nature of tobacco products was as important as information about the adverse effects tobacco use may have on one's health. Congress directed the Secretary to report every three years on the addictive nature of tobacco. Similar to the legislation requiring a report on health consequences, the Secretary was empowered with the authority to make recommendations on appropriate legislation.

Congress also mandated that the Secretary establish a program to in-

20. See 15 U.S.C. § 1335 (stating it is unlawful "to advertise cigarettes and little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission").
21. See id.
22. See JACOBSON & WASSERMAN, supra note 18, at 6.
24. See id.
25. See 42 U.S.C. § 290aa-2(b) (requiring that the report submitted to Congress describes "current research findings made with respect to drug abuse, including current findings on... the addictive property of tobacco").
27. See id.
form the public about the dangers of cigarette smoking.\textsuperscript{28} This legislation was not enacted until 1984,\textsuperscript{29} exactly twenty years after the Surgeon General first reported that smoking cigarettes may have adverse consequences on health.\textsuperscript{30} Among some of the provisions meant to effectuate the program, is the responsibility to conduct research on the connection between smoking and health,\textsuperscript{31} and to disseminate this data and information to the public through publications.\textsuperscript{32}

\textbf{B. Regulation of Smokeless Tobacco Products}

In 1986, Congress passed legislation on smokeless tobacco products that mirrors many provisions in the legislation affecting tobacco products that are smoked.\textsuperscript{33} For example, specific warning labels are to be affixed on packaging and on advertisements for smokeless tobacco products.\textsuperscript{34} Furthermore, the Secretary has the responsibility of implementing a program to inform the public about the dangers of using smokeless tobacco products.\textsuperscript{35} Advertising smokeless tobacco products on television is forbidden in the same way it is forbidden to advertise cigarette products.\textsuperscript{36}

\textbf{C. Recent Legislation of Tobacco Products}

One of the last pieces of legislation in Congress’ attempt to establish a comprehensive plan to decrease the rate of death and disease resulting from smoking was the 1992 Alcohol, Drug Abuse, and Mental Health

\begin{itemize}
  \item 29. \textit{See id.}
  \item 30. \textit{See supra} text accompanying note 13.
  \item 32. \textit{See id.} § 1341 (a)(4).
  \item 33. \textit{See} 15 U.S.C. § 4406 (defining smokeless tobacco as “any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity”).
  \item 34. \textit{See id.} § 4402 (a). The following warnings are to be used:
    “\textit{WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER},”
    “\textit{WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS},”
    “\textit{WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES},” \textit{id.}
  \item 35. \textit{See id.} § 4401.
  \item 36. \textit{See} 15 U.S.C. § 4402 (f) (stating that it is unlawful to advertise smokeless tobacco products on any medium of electronic communication regulated by the FCC); \textit{see also} 15 U.S.C. § 1335 (stating that it is unlawful to advertise cigarette products on any medium of electronic communication regulated by the FCC).
\end{itemize}
Agency Reorganization Act. This Act provides financial incentives to states to encourage them to enforce their own restrictions on access to tobacco products by minors. Each state that chooses to participate must enact legislation prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing to individuals under eighteen. In exchange, the federal government will allocate grants to participating states for use in the prevention and treatment of substance abuse. Once such state legislation is passed, future grants are awarded based on the state’s compliance with specific conditions. First, each state must conduct annual, random, unannounced inspections of manufacturers, retailers, and distributors to ensure compliance with the state’s statute. Second, each state must report its actions in enforcing such law, as well as the rate of success the state has achieved in reducing the availability of tobacco products to individuals under eighteen years of age. Failure to comply with the provisions of the Act will result in a ten percent decrease in funding for the first year of noncompliance, and up to forty percent by the fourth year of noncompliance.

II. GRANTING THE INDUSTRY IMMUNITY AS A MEASURE TO CONTROL TOBACCO USE

Before presenting an exposition of the measures to control tobacco use that comprises the focus of this Comment, it is important to note that the Failed Settlement proposed many measures not discussed in this Comment. This Comment’s focus will be on three issues: (1) the grant of immunity, (2) restrictions on advertising of tobacco products, and (3) the grant of jurisdiction to the FDA. Although the other measures not

38. See id. § 300x-26 (a)(1) (stating that “the Secretary may make a grant . . . only if the State involved has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute . . . to any individual under the age of 18”).
39. See id.
40. See id. The regulation at issue provides that grants will be made under 42 U.S.C. § 300x-21. See id. 42 U.S.C. § 300x-21 provides that the Secretary shall make grants for each State “for the purpose of planning, carrying out, and evaluating activities to prevent and treat substance abuse . . . .” Id. § 300x-21 (a).
41. See 42 U.S.C. § 300x-26 (2).
42. See id.
43. See id.
44. See id. § 300x-26 (c).
discussed are equally deserving of attention, the proposals discussed hereinafter were chosen as the focus because they were the center of much controversy and debate during negotiations.

A. Immunity as Envisioned in the Failed Settlement

The grant of immunity, as espoused in the Failed Settlement, was designed to settle the current claims against the tobacco manufacturers and insulate them from future litigation. Because an immunity provision would serve as a good incentive to encourage the Industry to settle with Congress, the Industry pushed for immunity during settlement negotiations. It is, therefore, important to evaluate the provision for such immunity as envisioned in the Failed Settlement bill. Should the Industry and Congress resume negotiations for a renewed settlement, many of the same terms may resurface.

The Failed Settlement included the following provisions: (1) the present state government suits would settle and similar state actions would be barred in the future;\(^45\) (2) all pending claims for addiction and dependency would terminate and the industry would be immune from future claims;\(^46\) (3) all pending class actions would terminate and the industry would be immune from future class actions;\(^47\) and (4) punitive damages would be eliminated for past conduct and maximum caps would be placed on the amount the Industry would be ordered to pay each year on judgments against it.\(^48\)

Although Congress tried to limit federal control over tobacco in the past,\(^49\) plaintiffs have never been barred from seeking restitution for harm caused by the tobacco companies. Since the 1950s, smokers have sought restitution from the tobacco industry for smoking-related diseases.\(^50\) Unfortunately for the plaintiffs, the Industry was successful in defending itself against such suits. Past tobacco litigation suits are clas-

\(^{45}\) See S. 1415, 105th Cong. § 601(a) (1997).

\(^{46}\) See id. § 601 (b)(2).

\(^{47}\) See id. § 601 (b)(1).

\(^{48}\) See id. § 602.

\(^{49}\) See supra Part I.

\(^{50}\) One of the first cases filed against the industry was Lowe v. R.J. Reynolds Tobacco Co., filed against a tobacco manufacturer in 1954. See Robert L. Rabin, A Sociological History of the Tobacco Tort Litigation, 44 Stan. L. Rev. 853, 857 (noting in an accompanying footnote that the case was subsequently dropped but that it was filed in the Eastern District of Missouri on March 10, 1954 as No. 9673(c)).
sified into three “waves,” and the characteristics that define each wave help to explain why earlier lawsuits brought against the Industry failed.

B. The First Wave of Litigation Against Tobacco Manufacturers

The first wave of tobacco litigation began in the early to mid 1950s. Generally, plaintiffs filed suits against the Industry under theories of negligence and breach of warranty. These lawsuits were not success-


52. See Kelder & Daynard, supra note 51, at 71 (stating that the first wave of tobacco litigation spanned from 1954 to 1973); see also Gary T. Schwartz, Tobacco Liability in the Courts, in SMOKING POLICY: LAW, POLITICS, AND CULTURE 131 (Robert L. Rabin & Stephen D. Sugarman eds., 1993) (stating that the causal connection between smoking and cancer was first publicized in the early 1950s, and that publicizing the connection led to a wave of lawsuits against tobacco companies); Christine Hatfield, Note and Comment, The Privilege Doctrines – Are They Just Another Discovery Tool Utilized By the Tobacco Industry to Conceal Damaging Information?, 16 PACE L. REV. 525, 561 (1996) (stating that the first wave of litigation began in the 1950s to early 1960s).

53. The definition of negligence is “the failure to use such care as a reasonably prudent and careful person would use under similar circumstances; it is the doing of some act which a person of ordinary prudence would not have done under similar circumstances . . . .” BLACK’S LAW DICTIONARY 1032 (6th ed. 1990). The elements necessary to prove a cause of action under a negligence theory are as follows: (1) the existence of a duty or an obligation requiring a person to conform to a certain standard of conduct; (2) a breach of the duty to conform to a certain standard of conduct; (3) a reasonably close causal connection between the breach of duty and the harm caused; and (4) actual loss or damage resulting from the breach of duty. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 30, at 164 (5th ed. 1984).

54. See Kelder & Daynard, supra note 51, at 71 (stating that during the first wave of suits “cases were filed principally under theories of . . . breach of express and implied warranty, and negligence”). Meade, supra note 51, at 114 (stating that in the first wave of litigation recovery was sought under breach of implied warranty and breach of express warranty). Implied warranty has been defined as “[a]n assurance or guaranty, either express in the form of a statement by a seller of goods, or implied by law, having reference to and ensuring the character, quality, or fitness of purpose of the goods.” BLACK’S LAW DICTIONARY 1586 (6th ed. 1990).
ful. One reason for this failure was that medical knowledge in the 1950s, and early 1960s, did not establish a link between tobacco use and health risks.\textsuperscript{55} Hence, plaintiffs were unable to prove that smoking was the proximate cause of the illnesses suffered.\textsuperscript{56}

In \textit{Ross v. Philip Morris},\textsuperscript{57} the plaintiff brought an action against a tobacco manufacturer for breach of implied warranty after developing throat cancer.\textsuperscript{58} The plaintiff argued that Philip Morris owed its consumers a duty to provide cigarettes that did not contain substances that were harmful or dangerous to their health.\textsuperscript{59} The plaintiff asserted that if the tobacco product contain harmful or carcinogenic substances that directly caused his cancer, Philip Morris should be held liable, irrespective of whether Philip Morris knew of the danger of the substance.\textsuperscript{60} Philip Morris contended that a manufacturer could be held liable under an implied warranty only for harmful defects that could be detected with reasonable foresight.\textsuperscript{61} The court held there was no breach of an implied warranty.\textsuperscript{62} The plaintiff presented no evidence that suggested that Philip

\begin{footnotesize}
\begin{enumerate}
\item See Kelder & Daynard, supra note 51, at 71 (stating that plaintiffs were "hampered by the paucity of medical studies"); see also Meade, supra note 51, at 119; see also Hatfield, supra note 52, at 561-62.
\item See Kelder & Daynard, supra note 51; see also Meade, supra note 51, at 119 (noting that the addictive nature of tobacco products was not fully recognized at the time and this led to the difficulties in linking smoking with injury).
\item 328 F.2d 3 (8th Cir. 1964).
\item See id. at 5. The plaintiff also brought action at the district court level for negligence, but on appeal to the Eighth Circuit the plaintiff sought no review of his negligence claim. See id.
\item See id. at 5-6. The plaintiff began smoking when he was twenty-eight or twenty-nine years old. See id. at 5. Several years later, he was smoking up to two packages of cigarettes a day. See id. His consumption increased to smoking between three and four packages daily. See id. When he was fifty-three years old he was informed that he had throat cancer, and a subsequent operation left the plaintiff breathing through an opening in his neck and speaking with the aid of an electronic device. See id.
\item See id. at 6.
\item See id. at 7. Philip Morris also argued that, under Missouri law, a tobacco manufacturer does not implicitly warrant its tobacco product, therefore, the issue should not be a jury consideration. See id. Furthermore, Philip Morris argued that the evidence admitted was insufficient to establish that smoking caused the plaintiff's cancer. See id.
\item See Ross, 328 F.2d at 12 (holding that the trial court correctly instructed the jury on the implied warranty issue).
\end{enumerate}
\end{footnotesize}
Morris was aware that its product contained a cancer-causing agent. Furthermore, the cigarettes that Philip Morris manufactured were not adulterated or defective. Rather, they were reasonably fit for intended use. As a result, Philip Morris could not be charged with having knowledge that harmful or dangerous substances were contained in its product, therefore, no liability was imposed.

Likewise, in Lartigue v. R.J. Reynolds Tobacco Co., the plaintiff brought an action against a cigarette manufacturer for negligence in failing to warn the public that the use of its product could cause cancer. The jury delivered a verdict in favor of the defendants. The plaintiff appealed the decision because he believed the instruction given to the jury on negligence was in error. The Fifth Circuit disagreed, holding that the charge correctly instructed that in order to impose liability for negligence, Mr. Lartigue must prove that the defendant knew, or should have known, that its product could cause cancer before his illness started. The instruction further charged that, under the facts of this case, such knowledge could only be imputed to R.J. Reynolds if medical science concluded and publicized information linking cancer and smoking. Because the medical community had no such knowledge

63. See id. at 10 (stating that “plaintiff’s position is that . . . even though there may have been no immediate harm from smoking a package of cigarettes, . . . and even though no developed human skill or foresight could afford knowledge of the cancer-smoking relationship, defendant should be held absolutely liable . . .”).
64. See id. at 9. The plaintiff failed to show that Philip Morris’ cigarettes, in particular, contained a foreign or deleterious substance that caused cancer. See id. The plaintiff did not contend that the Philip Morris cigarettes did not conform to industry standards. See id.
65. See id. at 9-10.
66. See id. at 12-13 (stating that a cigarette “manufacturer . . . is held as an absolute insurer against knowable dangers . . .”).
67. 317 F.2d 19 (5th Cir. 1963).
68. See id. at 40. Action was also brought under an implied warranty theory. See id. at 22. The plaintiff argued that the trial judge’s charge to the jury was misleading on the implied warranty theory because they were so interfused with negligence principles. See id. at 23. The Fifth Circuit held that the instruction on implied warranty was correct; the trial judge differentiated between the implied warranty claim and the negligence claim. See id. at 24.
69. See id. at 22.
70. See id. at 40.
71. See id. at 39-40.
72. See Lartigue, 317 F.2d at 40. (“The defendants cannot be held guilty of negligence on the basis of medical opinion, surveys, or other similar materials not
at that time, the plaintiff could not establish the causal connection essential to any negligence claim.33

Another reason the tobacco companies were successful in refuting claims during this first wave of litigation was because they had the financial resources to employ effective defense strategies and limit the number of lawsuits filed against them.74 Collectively, each tobacco company vowed not to settle any dispute because each company maintained that they were not responsible for any injury sustained as the result of using their products.75 That decision meant they would defend themselves against every claim through a trial and any appeal, irrespective of costs.76 The cigarette companies were well aware that one settlement would lead to the filing of thousands of similar claims.77 To protect itself from damaging lawsuits, the Industry retained high paid defense attorneys from prestigious law firms, mailed plaintiffs extensive interrogatories, and took mass depositions.78 Costly expert witnesses also became an important part of trial.79 Obtaining expert testimony to establish the causal link between smoking and adverse health consequences imposed a significant burden on the plaintiffs.80 In sum, the litigation strategies employed by the Industry illustrated how the cigarette companies were formidable figures that were too powerful and too wealthy for plaintiffs to battle.

announced until after that time.").

73. See id.
74. See Kelder & Daynard, supra note 51, at 71; Hatfield, supra note 52, at 562.
75. See Rabin, supra note 50, at 857.
76. See id.
77. See id.
78. See id. at 858-59; Hatfield, supra note 52, at 562.
79. See, e.g., Lartigue v. R.J. Reynolds, 317 F.2d 19, 22-23 (5th Cir. 1963) (pointing out that the record comprised twenty volumes; chemical studies were admitted, as well as "epidemiological studies, reports of animal experiments, pathological evidence, reports of clinical observations, and the testimony of renowned doctors").
80. See Rabin, supra note 50, at 858 (noting that the expense was due, in part, to the travel time, witness fee, and time-related costs in keeping them available for testimony).
The second wave of litigation began in 1983. Among some of the claims plaintiffs asserted were product liability, negligence, strict liability, and failure to warn. Many factors prompted the second wave that were not present twenty years earlier during the first wave of litigation. One such factor involved society’s perception of cigarette smoking. The unknown risks associated with smoking probably increased the social acceptability of smoking during the first wave. This, in turn, increased the difficulties of litigating successful claims. During the second wave of lawsuits, the idea of smoking a cigarette was not as socially acceptable as it had been in the past. In addition, large law firms, experienced in sophisticated tort litigation, were trying cases against the tobacco industry, as opposed to sole practitioners litigating in the first wave of suits. Now, large parties were joining collectively,
pooling their money, personnel, and technical expertise.  

One of the more important factors, however, separating the first wave of litigation from the second was the availability of medical studies to establish the causal connection between smoking and disease. Because the medical risks associated with smoking were more pronounced than in previous years, it would have seemed likely that plaintiffs would have been more successful at imputing liability to the tobacco industry. Yet, the plaintiffs did not succeed. In fact, the more acute medical knowledge about the dangers of smoking served as a detriment to the plaintiffs in arguing their claims. The more people knew about the risks associated with tobacco use, the easier the Industry could argue that smoking was a deliberate, conscientious decision.  

In *Roysdon v. R.J. Reynolds Tobacco Co.*, for example, the plaintiff argued that R.J. Reynolds failed to warn him that he could be at risk for vascular disease. Although the FCLAA mandates that specific warnings be printed on cigarette packages, none of the warnings specifically address the potential for developing vascular disease. Despite the fact that the plaintiff introduced evidence linking smoking to vascular disease, his failure to warn claim was dismissed. The Sixth Circuit held that the claim was preempted by the FCLAA because the Act specifies that no other statement relating

90. *See id.* (describing that the extent of the cooperation by attorneys for the plaintiffs reached national proportions and that the larger firms had the “financial, technical, and manpower resources necessary to go the distance”).

91. *See Kelder & Daynard, supra note 51, at 71; see also Meade, supra note 51, at 122.*

92. *See Kelder & Daynard, supra note 51, at 71; see also Meade, supra note 51, at 122.*

93. *See Rabin, supra note 50, at 870 (stating that the most prominent theme threaded through the spectrum of second wave cases was the argument that, despite the warnings, people who smoked did so by deliberate, conscious choice).*

94. 849 F.2d 230 (6th Cir. 1988).

95. *See id.* at 232. The plaintiff, Mr. Roysdon, was an addicted smoker who had severe peripheral atherosclerotic vascular disease. *See id.* His left leg had to be amputated because his disease prevented his foot from properly healing from a surgical procedure he underwent. *See id.*

96. *See discussion supra Part I.*


98. *See id.* at 232.

99. *See id.*

100. *See id.* at 235.
to smoking and health shall be required other than those mandated.\textsuperscript{101} If a jury were to find that the tobacco manufacturer, by complying with the terms of the FCLAA, failed to warn its consumers of inherent product risks, then the congressional intent behind the FCLAA would be threatened.\textsuperscript{102}

In \textit{Roysdon}, the Sixth Circuit also addressed a product liability claim.\textsuperscript{103} The court applied Tennessee law, which stated that a manufacturer would be held liable if a product was in a “defective condition” or was “unreasonably dangerous.”\textsuperscript{104} The court concluded that the cigarette products met neither of these definitions\textsuperscript{105} and affirmed the directed verdict in favor of the defendants.\textsuperscript{106} Consumers were well aware of the risks associated with smoking.\textsuperscript{107} There was no proof that the cigarettes were improperly manufactured or that they presented greater risks than those known to be associated with smoking.\textsuperscript{108} Moreover, the risks associated with smoking were common knowledge, and there was extensive information regarding the dangers.\textsuperscript{109}

In \textit{Gilboy v. American Tobacco Co.},\textsuperscript{110} the plaintiff, a lifetime smoker diagnosed with cancer, brought a cause of action under theories of product liability and strict liability.\textsuperscript{111} The court affirmed summary judgment

\begin{thebibliography}{99}
\bibitem{101} See id. at 233 (quoting 15 U.S.C. § 1334 (1982)).
\bibitem{103} The purpose of Congress, in enacting FCLAA, was to inform the public about the dangers of cigarette smoking as well as protect the national economy. See \textit{id.} at 234 (quoting 15 U.S.C. § 1331 (1982)). Congress would not have intended for its balance of nations interests to be superceded by the views of a single jury in a single state. See \textit{id.} at 234 (quoting Palmer v. Liggett Group, Inc., 825 F.2d 620, 626 (1st Cir. 1987)).
\bibitem{104} See \textit{id.} at 236.
\bibitem{105} See \textit{id.} at 235-36.
\bibitem{106} Under Tennessee law, a “defective condition” is defined as “a condition of a product that renders it unsafe for normal or anticipatable handling and consumption.” \textit{Id.} at 236 (quoting Tenn. Code Ann. § 29-28-102(2)). Under Tennessee law, an “unreasonably dangerous” product is one that “is dangerous to an extent beyond that which could be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to the community as to its characteristics.” \textit{Id.} (quoting Tenn. Code Ann. § 29-28-102(8)).
\bibitem{107} See \textit{id.} at 236.
\bibitem{108} See \textit{id.}
\bibitem{109} See \textit{id.}
\bibitem{110} 572 So. 2d 289 (La. Ct. App. 1990).
\bibitem{111} See \textit{id.} at 289-90.
\end{thebibliography}
in favor of the defendants and denied recovery on the plaintiff’s claims.\textsuperscript{112} The plaintiff asserted in the strict liability claim that smoking is an ultra-hazardous activity.\textsuperscript{113} The court rejected this claim because smoking cigarettes involves an individual consumer choice to do so. Unlike other ultra-hazardous activities, smoking cigarettes does not involve a risk dangerous enough that the tobacco manufacturer would assume the consequences of injury to others.\textsuperscript{114}

In rejecting the plaintiff’s product liability claim, the court recognized that product liability involves compensating individuals for injuries sustained as the result of defects in a manufacturer’s product.\textsuperscript{115} The court pointed out that use of a tobacco manufacturer’s product does not cause harm that consumers could not have anticipated.\textsuperscript{116} It was widespread knowledge that cigarettes are dangerous to one’s health.\textsuperscript{117} Moreover, there are sufficient warning labels on the packaging that raise awareness of the risks.\textsuperscript{118} By smoking, therefore, the plaintiff made a conscious decision and must bear the consequences of such deliberated action.\textsuperscript{119}

\textbf{D. The Promise the Third Wave of Litigation Has for Plaintiffs}

\textit{1. State-Initiated Medicaid Suits: The Third Wave of Litigation}

The suits filed by state attorneys general to recover Medicaid ex-

\begin{itemize}
\item[112.] See id. at 290 (noting that the defendant’s motion for summary judgment asserted that the plaintiff failed to state a claim under Louisiana’s Product Liability Law and that the plaintiff’s negligence claim was preempted by the FCLAA).
\item[113.] See id.
\item[114.] See id.
\item[115.] See Gilboy, 572 So. 2d at 290.
\item[116.] See id.
\item[117.] See id.
\item[118.] See id. at 290-91.
\item[119.] See id. at 291. The court used strong language in addressing the reasons why the plaintiff failed to state a claim. See id. The court said, “The law would protect [the plaintiff] from a product that had a hidden defect. The law would protect [the plaintiff] from a product that lacked an adequate warning. The law would even protect [the plaintiff] from harm arising from the misuse of a defective product. However, the law will not protect [the plaintiff] from himself.” Id. at 291-92.
\end{itemize}
expenses, that prompted the negotiations to the Failed Settlement, are examples of the types of cases in the third wave of litigation. Most complaints by the states allege, \textit{inter alia}, that the Industry is guilty of fraudulent misrepresentation and breach of warranty. Common to many of the complaints, however, are the theories of unjust enrichment and conspiracy.

In order for a state to prove that the tobacco companies were unjustly enriched, it must be established that the tobacco companies received enormous profits through the sale of their products to addicted smokers. When addicted consumers developed serious medical problems, the state paid for their treatment through its Medicaid program. Consequently, the tobacco companies were unjustly enriched by avoiding health care costs incurred as a result of the use of their products.

To show that the tobacco manufacturers are liable for conspiracy, it may be necessary to show that the manufacturers, with intent and unlawful purpose, entered in a concert of action to misrepresent the degree of

\begin{itemize}
\item 120. See Kelder & Daynard, supra note 51, at 73; see also Meade, supra note 51, at 124.
\item 121. Fraudulent misrepresentation is defined as a false statement as to a material fact that is made with the intent that the other party rely on it and the other party does, indeed, rely and does so to their detriment. See \textsc{Black's Law Dictionary} 662 (6th ed. 1990).
\item 122. Breach of warranty is defined as a breach in the assurance or guaranty made by the producer of a good that the good sold has certain qualities, fitness, or characters. See \textsc{Black's Law Dictionary} 1586 (6th ed. 1990). Warranties on goods sold may be either express or implied. See id. at 1586-87. An express warranty is a promise that is ancillary to an underlying sales contract in which the seller assures the qualities, description, or performance of the good. See id. at 1587. An implied warranty is a promise that arises through operation of law which assures that the good sold is merchantable and fit for purpose. See id.
\item 123. The theory behind the principle of unjust enrichment is that one person should not be able to unjustly enrich himself at the expense of others. See \textsc{Black's Law Dictionary} 1535 (6th ed. 1990). If a party has been found to be unjustly enriched at the expense of another, restitution should be made for benefits received. See id.
\item 124. Conspiracy, in the context of a civil lawsuit, has been defined as "a concert or combination to defraud or cause other injury to person . . . , which results in damage to the person . . . of plaintiff." \textsc{Black's Law Dictionary} 310 (6th ed. 1990).
\item 125. See Kelder & Daynard, supra note 51, at 81.
\item 126. See id.
\end{itemize}
harm tobacco use could cause.\textsuperscript{127} It may be necessary to establish that the Industry suppressed research and prevented the dissemination of information on the harmful effects of tobacco use.\textsuperscript{128}

2. The Promise the Third Wave Holds for Imputing Liability on the Industry

Notwithstanding the difficulty in litigating the first and second waves,\textsuperscript{129} the third wave of litigation appears to be the most promising for plaintiffs. Such success will be thwarted, however, if an immunity provision similar to that previously negotiated in the Failed Settlement is implemented into a program to reduce tobacco use. If there is to be any progress in controlling tobacco use in this country, it is imperative that the Industry receive no immunity from liability.

Any victory in the current wave of litigation will have devastating financial effects on the Industry.\textsuperscript{130} Because of the difficulty the Industry will have in defending itself against state Medicaid reimbursement suits, most of the economic burden for treating smoking-related illnesses will be diverted to the tobacco companies.\textsuperscript{131} At present, the Industry faces mounting litigation.\textsuperscript{132} Most states filed claims against the Industry, and other pending lawsuits have been initiated by members of the private sector.\textsuperscript{133}

Because of the intense litigation facing the tobacco companies, they would want an immunity provision should Congress and the Industry resume settlement negotiations. In fact, it is possible the Industry is

\begin{itemize}
\item \textsuperscript{127} See id.
\item \textsuperscript{128} See id.
\item \textsuperscript{129} See supra Parts II.B., II.C.
\item \textsuperscript{130} See Kelder & Daynard, supra note 51, at 70; see also Lynn M. LoPucki, Some Settlement, WASH. POST, Jan. 21, 1998, at A15 (stating that the amount of damages sought in the current lawsuits against the industry exceeds the entire value of the tobacco companies). See, e.g., The Big Numbers of 1997 Verdicts, 20 NAT’L L. J. Feb. 23, 1998, at C15 (reporting that the tobacco industry settled its lawsuit with the state of Florida for $11.3 billion and settled with Mississippi for $3.6 billion).
\item \textsuperscript{131} See LoPucki, supra note 130, at A15.
\item \textsuperscript{133} See id. (detailing the other lawsuits that were filed, including pending claims from unions to recover on behalf of union members, public actions from cities like Los Angeles and San Francisco, and private claims from individuals).
\end{itemize}
aware of the promise the third wave of litigation has for state plaintiffs and that this realization was what prompted the initial settlement discussions.\(^{134}\)

3. The Secret to the Success of Third Wave Litigation Suits

One reason for the projected success of the third wave is the release of confidential documents to the public showing that the tobacco manufacturers knew their products were addictive and hid their knowledge from consumers.\(^{133}\) This evidence may effectively establish that the Industry is liable, at a minimum, of conspiring to lure young adults to use and, ultimately, addict them to tobacco products. It may also establish that tobacco manufacturers intentionally misrepresented to the public the effects using their products would have on health.

Some of the documents show that tobacco manufacturers specifically targeted teenagers in order to secure the demand for their products in the future.\(^{136}\) For example, documents from R.J. Reynolds strongly support the contention that the “Joe Camel” image was designed to appeal to children.\(^{17}\) The documents unequivocally reveal that R.J. Reynolds executives knew that the best way to continue the prosperity of their com-

134. See Hanson & Logue, supra note 51, at 1320; see also Conason & Hershenhorn, supra note 132, at S12.


136. One memo originating from a Board of Directors meeting at R.J. Reynolds dated Sept. 30, 1974, outlined the company’s plans for future marketing strategies. Memos Highlight Importance of ‘Younger Adult Smokers’, supra note 135, at A18. “We will speak to ... key opportunity areas to accomplish this [goal of reestablishing R.J. Reynolds’ share of marketing growth in the domestic cigarette industry]. They are: (1) Increase our young adult franchise.” Id.

137. See Internal R.J. Reynolds Documents Show That Marketing Proposals Targeted Children, supra note 135, at A18 (quoting directly from memos released in January 1998 from R.J. Reynolds archives). Although none of the released documents explicitly say that Joe Camel was meant to attract children, the campaign was based on an advertising stunt in France. See id. The advertising campaign in France was a huge success among children/teenagers. See id. Additionally, an R.J. Reynolds memo from an official at the company said “the French campaign was ‘about as young as you can get, and aims right at the young adult smoker Camel needs to attract.’” Id. (quoting from a 1974 R.J. Reynolds memo).
pany was to target the youth of America.\textsuperscript{138}

Documents were also released from other tobacco companies detailing their strategies to target young smokers. One internal memo from Philip Morris, for example, details the company's surge to attract consumers as young as twelve years old in efforts of securing the demand for its product in the future.\textsuperscript{139} The documents show that Philip Morris was concerned that the rate of teenage smoking in the mid-1970s declined.\textsuperscript{140} They knew they had the highest share of youth smokers than any other manufacturer and such a decline would hurt the future success of their business.\textsuperscript{141}

Documents from Brown & Williamson were also released to the public detailing its attempt to target youth smokers.\textsuperscript{142} One memo was particularly egregious in that it suggested adding an ingredient to sweeten the taste of its tobacco products because teenagers enjoy sweet tasting products.\textsuperscript{143} Another memo from their vestiges recommended that the company should not avoid changing the understanding that smoking is dangerous.\textsuperscript{144} Instead, focus should be on making smoking out to be in an illicit category of vices, like beer and sex, in order to encourage its

\begin{quote} \textsuperscript{138} “Realistically, if our Company is to survive and prosper, over the long term we must get our share of the youth market. . . . This will require new brands tailored to the youth market; . . . ” \textit{Id.} (quoting from a Feb. 2, 1973, memo written by R.J. Reynolds senior researcher Claude Teague). “[R.J. Reynolds] should not in any way influence non-smokers’ to start smoking; rather we should simply recognize that many or most of the ‘21 and under’ group will inevitably become smokers, and offer them an opportunity to use our brands.” \textit{Id.} (quoting from a Feb. 2, 1973, memo written by R.J. Reynolds senior researcher Claude Teague). “[The young adult market in the 14-24 age group] represent tomorrow’s cigarette business. As this 14-24 age group matures, they will account for a key share of the total cigarette volume – for at least the next 25 years . . . .” \textit{Id.} (quoting from a presentation to R.J. Reynolds board of directors meeting, dated Sept. 30, 1974).

\textsuperscript{139} See Schwartz, \textit{supra} note 135, at A15 (quoting from an internal document from Philip Morris stating that “today’s teenager is tomorrow’s potential regular customer”).

\textsuperscript{140} See \textit{id.} (citing from a March 1981 memo to the vice president of Philip Morris).

\textsuperscript{141} See \textit{id.} (describing the decline in youth smokers from 1976-77 as “troubling” in the memo to vice president of Philip Morris).

\textsuperscript{142} See \textit{id.} at A3.

\textsuperscript{143} See \textit{id.}

\textsuperscript{144} See \textit{id.}
use.\textsuperscript{145}

4. \textit{Why Giving the Tobacco Industry Immunity Would Be Detrimental to the Fight Against Tobacco}

Granting immunity to the Industry virtually obliterates any incentive to litigate against the tobacco industry.\textsuperscript{146} Barring plaintiffs from instituting class action suits in the future as well as state-initiated Medicaid reimbursement suits would leave the sole plaintiff to litigate against the entire industry. The history of the first wave of litigation demonstrated that fighting the tobacco industry alone is a losing battle.\textsuperscript{147} Without strong claimants who can withstand intense litigation, the tobacco industry would be empowered with the ammunition necessary to remain a formidable and powerful defendant.

The provision in the Failed Settlement that eliminates punitive damages for past conduct would also deter a sole plaintiff from bringing a suit against the Industry.\textsuperscript{148} In fact, this provision would decrease the incentive to sue the tobacco industry to a greater extent than the elimination of future class actions and State Medicaid suits.\textsuperscript{149} Once again, history has shown that the tobacco industry is too wealthy to fight without the incentive of receiving a large recovery through punitive damages.\textsuperscript{150} Long depositions are costly, interrogatories are time-consuming, and expert witnesses are often difficult to find. With the financial incentive reduced, a plaintiff may not be financially capable of litigating a claim they believe would be successful.

If a settlement passes with a similar immunity provision in the future, the Industry will have been successful at crafting pro-tobacco laws under the guise of tobacco control measures. It will be immune from having to pay millions of dollars to each individual litigant who may have a viable claim against it. It will also be able to keep out the confidential documents that pose a serious threat to its continued prosperity.\textsuperscript{151} If the incentive to sue is thwarted by a settlement that includes an immunity provision, so will the incentive to use the documents against the Indus-

\begin{itemize}
  \item \textsuperscript{145} See Schwartz, supra note 135, at A3.
  \item \textsuperscript{146} See Hanson & Logue, supra note 51, at 1320.
  \item \textsuperscript{147} See supra Part II.B.
  \item \textsuperscript{148} See Hanson & Logue, supra note 51, at 1320.
  \item \textsuperscript{149} See id.
  \item \textsuperscript{150} See supra Part II.B. (detailing how the Industry used trial tactics that decreased the financial incentives for plaintiffs to pursue suits against it).
  \item \textsuperscript{151} See Hanson & Logue, supra note 51, at 1320.
\end{itemize}
The strongest, most direct evidence against the Industry is its own admission of culpable and deceptive conduct. Although the documents were released to the public, they are useless if they cannot be used against the Industry in litigation.

III. IMPLEMENTING ADVERTISING RESTRICTIONS ON THE TOBACCO INDUSTRY AS A MEASURE TO CONTROL TOBACCO USE

A. Restrictions Proposed Under the Failed Settlement

Tobacco products are heavily advertised and widely promoted products in the United States. The restrictions on advertising in the Failed Settlement constituted some of the most radical restrictions of all the provisions. The scope of the restrictions is unprecedented when compared to previous advertising bans. Although television and radio were eliminated as advertising forums for tobacco products early in the history of federal tobacco control laws, that restriction occurred almost thirty years ago. Similar restrictive measures to control advertising have not been taken since then. There is a strong correlation between advertising and increased demand for tobacco products. If any of the restrictions proposed in the Failed Settlement were implemented in the future, they could reduce tobacco use significantly. For this reason, the ad restrictions in the Failed Settlement merit analysis.

Although not an exhaustive list, the Failed Settlement included the following: (1) a ban on all outdoor advertising as well as indoor advertising that is directed outside, (2) a ban on the use of human images and cartoon characters in all advertising and packaging, (3) a ban on advertising on the Internet, (4) a requirement that advertising exposed to children be on a black-and-white background, with a text-only format, except in publications where the readership of individuals eighteen years of age or younger is, at most fifteen percent, but fewer than two million young readers, (5) a prohibition on the sale or distribution of promo-

152. See id.
154. See supra Part I.A.
155. See supra Part I.
156. See id.
tional, non-tobacco related items, such as tee-shirts and hats, (6) a prohibition on any direct or indirect payments in efforts of glamorizing the image of tobacco use in the media that appeal to children, including any live music performances, (7) a prohibition on allowing manufacturers to sponsor any musical, athletic, artistic or social event in which the brand name, logo or other indicia of product identification is used, and (8) a requirement that product descriptors, like "light" or "low tar," be accompanied by disclaimer that the brand has not been shown to be less hazardous than other brands. 

B. Restrictions on Advertising Implicate First Amendment Commercial Speech Concerns

If Congress mandated advertising restrictions, First Amendment commercial speech concerns must be considered. Commercial speech is defined as expression that relates to the economic interests of its speaker, including advertisements for products or services. Because tobacco advertisements propose a commercial transaction, they are within the protection of the First Amendment. Historically, the Supreme Court held that the First Amendment did not provide protections for commercial speech. Commercial advertising did not implicate the constitutional protection of the First Amendment. As a result, courts gave state and federal legislatures a significant amount of deference in

159. Although the Supreme Court was not explicit in its definition of commercial speech, the cases involving First Amendment Commercial Speech considerations have involved product advertising. See, e.g., 44 Liquormart v. Rhode Island, 517 U.S. 484 (1996) (deciding whether a Rhode Island law banning the advertising of retail liquor prices is constitutional).
160. See Valentine v. Chrestensen, 316 U.S. 52, 54 (1942) (stating that the Constitution "imposes no such restraint on government as respects purely commercial advertising"); see also Bread v. Alexandria, 341 U.S. 622, 642-43 (1951) (upholding a conviction for violation of an ordinance prohibiting door-to-door solicitation of magazine subscriptions); JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW, § 16.27, at 1011-12 (West Publishing, 4th ed. 1991) (noting that in the years after the Chrestensen decision, later cases relied on the Supreme Court’s pronouncement to exclude commercial speech from any protection of the First Amendment).
161. See Valentine, 316 U.S. at 54.
restricting commercial speech to protect the public.\textsuperscript{162}

It was not until the Court decided \textit{Virginia Board of Pharmacy v. Virginia Citizens Consumer Council}\textsuperscript{163} that commercial speech was brought within the parameters of the First Amendment. At issue in \textit{Virginia Board of Pharmacy} was a statute prohibiting pharmacists from advertising prices for prescription drugs in an effort to maintain high standards of professional conduct for its licensed pharmacists.\textsuperscript{164} Even though the speech only proposed a commercial idea, the Court indicated that such speech had some value in the marketplace of ideas.\textsuperscript{165} The public had a First Amendment interest in the free flow of truthful information about lawful activity.\textsuperscript{166} Furthermore, the public's interest outweighed paternalistic interests the state had in maintaining high professional standards for pharmacists.\textsuperscript{167} The public had an interest in making intelligent and well-informed economic decisions. Advertising is the dissemination of information,\textsuperscript{168} therefore, the free flow of commercial information is indispensable in achieving that end.\textsuperscript{169}

\textbf{C. The Constitutional Test for Commercial Speech Concerns}

\textbf{1. Central Hudson's Four-Prong Test}

The Supreme Court developed a four-part test to analyze whether restrictions on commercial speech violated the First Amendment in \textit{Cen-}

\begin{itemize}
\item \textbf{162. See id.}
\item \textbf{163. 425 U.S. 748 (1976).}
\item \textbf{164. See id. at 749-50.}
\item \textbf{165. See id. at 764.}
\item \textbf{166. See id.}
\item \textbf{167. See id. at 766-67.}
\item \textbf{168. See Virginia Bd. of Pharmacy, 425 U.S. at 765 ("Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price."); see also 44 Liquormart v. Rhode Island, 517 U.S 484, 496-97 (1996) (quoting Virginia Bd. of Pharmacy, 425 U.S. at 765) (reemphasizing the assertion that commercial speech is the dissemination of information despite the potential for excess and tastelessness).}
\item \textbf{169. The Court reasoned that the market-place is a forum in which ideas and information flourish. Virginia Bd. of Pharmacy, 425 U.S. at 762. The speaker and the audience have the right to assess the value of the information expressed and not the government. See id.}
\end{itemize}
Measures to Control Tobacco Use

A regulation promulgated by the State Public Service Commission banned all public utility advertising that promoted the consumption of electricity. The Court held that the regulation was invalid because the state failed to show that a more limited speech regulation would not have served its interest. Government regulations on commercial speech must meet the following four-part analysis to be valid: (1) the expression must concern lawful activity and must not be misleading; (2) the asserted governmental interest must be substantial; (3) the restriction must directly advance the interest; and (4) the regulation must not be more extensive than necessary to serve the governmental interest.

It is this idea, that commercial speech protects the interests of the advertiser-speaker, as well as the audience-listener, that will subject the advertising restrictions on tobacco to First Amendment scrutiny. The tobacco industry may waive its right to argue any First Amendment claim by agreeing to the terms of a settlement. Yet, that is not to say that by agreeing to advertising restrictions, all First Amendment scrutiny disappears. The consuming public will have standing to sue, irrespective of whether the restrictions are adopted through negotiations similar to the Failed Settlement or legislated without the consent of the tobacco industry. In fact, the plaintiffs in Virginia Board of Pharmacy were not licensed pharmacists, but they were consumers of prescription drugs who argued they had a right to be informed of the prices of the drugs they may need.

The analysis developed in Central Hudson serves as the current constitutional standard in determining whether a restriction on advertising tobacco products is lawful under the First Amendment. Subsequent

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171. See id. at 558.
172. See id. at 570-71 ("[I]n the absence of a showing that more limited speech regulation would be ineffective, we cannot approve the complete suppression of Central Hudson's advertising.").
173. See id. at 566.
176. Although the four-part test developed in Central Hudson has been narrowed, it still serves as the proper test to be used in an analysis of commercial speech restrictions. See Florida Bar v. Went For It, Inc., 515 U.S. 618, 623-24
Supreme Court decisions, however, have refined the Central Hudson test and will be discussed below.

a. The First Prong Under Central Hudson

As articulated in the four-part test, advertising must concern lawful activity and must not mislead consumers to be considered protected speech.\(^{177}\) The Court arrived at this conclusion by analyzing the nature of the speech that is at issue and the interest the government will serve by regulating it.\(^{178}\) For example, when advertising is misleading, the opportunity for consumers to make informed, intelligent decisions diminishes. The government, as the protector of the general welfare, must prevent the dissemination of information that is unlawful and deceitful.\(^{179}\) Such advertising may be prohibited entirely, and the speakers of the unlawful or deceitful advertising are not protected by the First Amendment whatsoever.\(^{180}\)

Tobacco advertising that reaches the adult population concerns lawful activity. However, it is unlawful in every state to sell tobacco products to children under the age of eighteen.\(^{181}\) Proponents of the advertising restrictions may argue that, to the extent the restrictions relate to the sale of the products to children, they are not speech protected by the First Amendment. This argument may attempt to provide a justification, albeit a weak one, for at least one of the bans that was negotiated in the Failed Settlement. It was suggested that the "Joe Camel" image was an advertising campaign designed to attract children to using tobacco products.\(^{182}\) If the documents released from the archives of the tobacco manufacturers show that cartoon images were used in their advertising ploys to attract children, then a ban on the use of cartoon images will not have to go through First Amendment analysis. Such a ban will be constitutional because it attacks an unlawful activity.

Arguing that a First Amendment analysis is unnecessary because the speech concerns unlawful activity, however, will not provide the strong-

\(^{177}\) See Central Hudson, 447 U.S. at 566.

\(^{178}\) See id. at 563.


\(^{180}\) See id.; see also Central Hudson, 447 U.S. at 563.


\(^{182}\) See supra Part II.D.3.
est support for upholding the advertising restrictions. After all, only one restriction promulgated from the Failed Settlement would have been constitutionally valid without having to go through a full *Central Hudson* analysis. The remaining restrictions would have been analyzed under the remaining prongs to determine their constitutionality. Therefore, the remaining three prongs of the *Central Hudson* test will be analyzed to evaluate whether the other proposed advertising restrictions in the Failed Settlement violate the First Amendment. This analysis begins with the second prong of the test which assumes that the speech is protected by the First Amendment and demands that the asserted governmental interest be substantial.183

**b. The Second Prong Under Central Hudson**

Proponents of the restrictions will argue that protecting children from the dangers of smoking is a substantial interest. Generally, issues surrounding the welfare of children receive special consideration by the Supreme Court.184 The Court has recognized that the legislature should safeguard children from abuse in an effort to ensure that they grow to be well-developed and independent citizens.185 In fact, the Court decided that children may have their freedom of choice limited due to their lack of experience and judgement.186 Proponents of advertising restrictions should argue that children should be safeguarded from the dangers of tobacco use in asserting their governmental interest. Advertising restrictions are necessary, therefore, because they are designed to dissuade children from making decisions that may be detrimental to their well-being.

Not only would the proponents have the support of the Supreme Court’s decisions in protecting children, but they also would have substantive evidence showing a correlation between youth smoking and subsequent addiction. One such piece of evidence includes the FDA’s

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183. See *Central Hudson*, 477 U.S. at 564.
184. See *New York v. Ferber*, 458 U.S. 747, 757 (1982) (“Accordingly, we [The Supreme Court] have sustained legislation aimed at protecting the physical and emotional well-being of youth even when the laws have operated in the sensitive area of constitutionally protected rights.”).
conclusion that nicotine is a pediatric disease.\(^{187}\) The Agency’s conclusion is supported by evidence that shows that most people who suffer from tobacco-related illnesses began using tobacco before reaching the age of eighteen.\(^{188}\) Children are beginning to use tobacco products at earlier ages than had once been reported.\(^{189}\) In fact, the FDA predicts that if the rate of young users continues to increase, there will be little chance for society to curb tobacco-related illnesses in the future.\(^{190}\) Because it is unlikely that individuals who did not begin smoking as adolescents will ever develop smoking habits in their adult lives, the incidences of tobacco-related illness will decrease if the rate of youth smokers declines.\(^{191}\)

c. The Third Prong Under Central Hudson

The third and fourth prongs of the Central Hudson test require that the governmental interest be directly advanced by reasonable means that are narrowly tailored.\(^{192}\) These prongs are concerned with the nexus between the legislature’s stated ends and the means chosen to realize those ends. To show that the restrictions would directly advance the government’s substantial interests, thereby satisfying the third prong of the test in Central Hudson, Congress must provide evidence of the correlation between marketing techniques and the increase of tobacco use among children. A regulation that affects commercial speech will not be sustained if it does not directly support the governmental interest. Specifically, the regulation must materially affect the interest.\(^{193}\) The Supreme

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\(^{188}\) See id. at 44398 (reporting that 88% of adults who have ever smoked had their first cigarette by the time they were eighteen).

\(^{189}\) See id.

\(^{190}\) See id. at 44399.

\(^{191}\) See id.


\(^{193}\) In Edenfeld v. Fane, 507 U.S. 761 (1993), the Court struck down a state ban against solicitation by certified public accountants for failing the third prong of Central Hudson. See id. at 767. The Court reasoned that the state bears the burden of showing that the regulation will advance its interest “to a material degree.” Id.; see Rubin v. Coors, 514 U.S. 476, 479 (1995) (invalidating a federal law that prohibited beer labels from displaying alcohol content on the ground that the restriction failed materially to advance the asserted state interest in preventing “strength war” among brewers and protecting the welfare of its citizens).
Court, however, had given state legislatures great deference in justifying the use of advertising restrictions.194 In *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*, a Puerto Rican statute restricted advertising of casino gambling aimed at residents of Puerto Rico.195 The Court upheld the restriction.196 When the Court analyzed the third prong of *Central Hudson* to determine the legitimacy of the statute, the Court readily accepted the legislature’s finding that exposing the citizens of Puerto Rico to advertising for the local casinos would increase gambling.197 In fact, the Court believed a connection could be established by the mere fact that the appellant-hotel/casino litigated the issue all the way to the Supreme Court.198 A connection between advertising and gambling must exist, the Court found, because Posadas would not contest the restriction unless it believed that not imposing the restriction would yield to an increase in sales.200 The Court did not suggest that empirical evidence establishing a connection between advertising and an increase in gambling was necessary. Nor did the Court look to any other authority to support the legislature’s proposition.

The *Posadas* decision encouraged courts to defer to a legislature’s finding that the chosen restriction will directly advance a state’s interests. However, in subsequent decisions, the Court has attempted to restrict the latitude *Posadas* afforded state and federal legislatures. In fact, the Court noted that *Posadas* erroneously applied the *Central Hudson* factors.201 One case where the Court tried to restrict the degree of deference to the legislature was *Edenfield v. Fane*.202 At issue in *Edenfield* was a ban prohibiting certified public accountants from engaging in direct, personal, uninvited solicitation of clients.203 The Court held that a legislature has the burden of justifying its restrictions by more than mere

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196. See id. at 330.
197. See id. at 348.
198. See id. at 341-42.
199. See id. at 342.
200. See *Posadas*, 478 U.S. at 342.
203. See id. at 763-64.
speculation or conjecture.204 The governmental body must show that the harms it is attempting to prevent are real and that the restrictions will alleviate them in a direct and material way.205 In striking down the state's restriction, the Court recognized that there was an absence of any studies or anecdotal evidence that may support the state's contention that the restriction directly advances the state's interest.206

There is substantial evidence that links advertising and smoking to minors. For restrictions to be imposed, it is not necessary to prove conclusively that the correlation exists with empirical evidence or that the restrictions will solve the problem of youth smoking.207 However, in light of the severity of the advertising restrictions, it may be necessary to show that they will significantly reduce tobacco consumption. In 44 Liquormart v. Rhode Island,208 the Court evaluated, inter alia, the effectiveness of a ban on advertising the prices of alcohol to reduce alcohol consumption.209 A plurality of the Court agreed that the evidence on the record supported a finding that such a ban will have some impact on alcohol consumption.210 However, the state would need to provide evidence that the ban would significantly reduce consumption.211 The plurality made its determination based, in part, on the stringency of the advertising restriction.212 In the context of tobacco advertising, many of the restrictions in the Failed Settlement included bans and prohibitions that

204. See id. at 770.
205. See id. at 770-71.
206. See id. at 771. But see United States v. Edge Broad. Co., 509 U.S. 418, 427-28 (1993) ("[I]f there is an immediate connection between advertising and demand, and the federal regulation decreases advertising, it stands to reason that the policy of decreasing demand for gambling is correspondingly advanced."). C.f. Rubin v. Coors, 514 U.S. 476, 488 (1995) (striking down a section of the Federal Alcohol Administration Act that prohibited beer labels from displaying alcohol content because the government failed to demonstrate that this restriction would alleviate the stated harm to a material degree).
207. See Edge Broad. Co., 509 U.S. at 434 (1993) (stating that the Government may still advance its interests through regulation even though the problem is not eradicated entirely).
209. See id. at 505.
210. See id. at 506.
211. See id.
212. See id. at 505 ("The need for the State to make such a showing is particularly great given the drastic nature of its chosen means – the wholesale suppression of truthful, non-misleading information.").
would have greatly restricted the way tobacco manufacturers advertise. As a result of such stringent demands on the Industry, the Court would expect Congress to show that the restrictions on tobacco advertising will significantly reduce consumption by minors market-wide should similar restrictions be imposed on the Industry in the future.

There is research available that shows a connection between advertising and demand for tobacco products by children.213 It has been established that cigarette advertising actually encourages young people to smoke, and that the only effective way to combat this problem, is to institute bans on advertising from tobacco manufacturers.214 Despite R.J. Reynolds' claim that the image of "Joe Camel" was created to lure adults to switch to its Camel brand of cigarettes, researchers concluded that "Joe Camel" advertising was more successful at marketing Camel cigarettes to children than to adults.215 The available research shows that during the first three years of the "Joe Camel" advertising campaign, the proportion of youth smokers purchasing Camels rose from 0.5% to 32.8%.216 In fact, children twelve to thirteen years old registered the greatest recognition of advertising images.217 Not only is there informa-

214. See Pierce, et al., supra note 213, at 3154.
215. See DiFranza, et al., supra note 213, at 3149. The objectives of the study conducted by Joseph R. DiFranza, John W. Richards, Jr., M.D., Paul M. Paulman, M.D., Nancy Wolf-Gillespie, M.A., Christopher Fletcher, M.D., Robert D. Jaffe, M.D., David Murray, Ph.D. was to determine if R.J. Reynolds' cartoon-theme advertising is more effective at promoting Camel cigarettes to children than to adults. See id. at 3149. The subjects of the study were high school students from five regions of the United States as well as adults over the age of twenty-one from Massachusetts. See id. The results of the study indicate that children were better able to identify the tobacco product that was being advertised. See id. Children were more attracted to Camel cigarettes than adults. See id. Furthermore, Camel's share of the market to children rose from 0.5% to 32.8%. See id.
216. See id. at 3151.
217. See Pierce et al., supra note 213, at 3157. The participants of the study conducted by John D. Pierce, Ph.D., Elizabeth Gilpin, M.S., David M. Burns, M.D., Elizabeth Whalen, M.A., Bradley Rosbrook, M.S., Donald Shopland, Michael Johnson, Ph.D., were 24,296 adults and 5,040 teenagers. See id. at 3154. The study was conducted using telephone survey data compared with data from a 1986 telephone survey study. See id.
tion that directly links increased advertising with increased sales, but there is also evidence that shows children, in particular, are attracted and vulnerable to advertising techniques used by the tobacco industry.\textsuperscript{218}

Limiting the advertisement of tobacco products to black-and-white background, text-only format, and eliminating characters like "Joe Camel," may directly reduce the number of youth smokers.

d. The Fourth Prong Under Central Hudson

The fourth prong of the \textit{Central Hudson} test is satisfied when it is determined that the restrictions are not more extensive than necessary.\textsuperscript{219}

Regulations on commercial speech cannot completely suppress information when a more narrowly tailored restriction would serve the state's interest as effectively.\textsuperscript{220}

Subsequent Supreme Court decisions shaped the fourth prong of the \textit{Central Hudson} test to make it easier for the states or Congress to regulate commercial speech. The Court held that the fourth prong of the test only requires a \textit{reasonable} fit between a state's interests and the means chosen to advance those interests.\textsuperscript{221} It is not necessary that the means be the least restrictive means available nor must they be the best possible restrictive measure. The chosen means need only be narrowly tailored.\textsuperscript{222}

The \textit{Posadas} decision suggested that state and federal legislatures have discretion in determining the appropriate measures to apply in advancing their interests.\textsuperscript{223} Since \textit{Posadas}, however, the Court has tried to

\begin{itemize}
\item \textsuperscript{218} David A. Locke, \textit{Counterspeech as an Alternative to Prohibition: Proposed Federal Regulation of Tobacco Promotion in American Motorsport}, 70 \textit{IND. L.J.} 217, 226 (1994).
\item \textsuperscript{220} See id. at 565.
\item \textsuperscript{221} See Bd. of Trustees of the State Univ. of New York v. Fox, 492 U.S. 469, 480 (1989).
\item \textsuperscript{222} See id. (stating that there must be a fit between the legislature's means and goals, "a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is "in proportion to the interest served""") (citing \textit{In re R.M.J.}, 455 U.S. 191, 203 (1982)). The state is not obligated to choose the least restrictive means available, but it must be narrowly tailored. See id. The scope of the restriction must be reasonable, and does not need to be perfectly targeted to address the harm intended to be regulated. See id.
\item \textsuperscript{223} See \textit{Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico}, 478 U.S. 328, 346 (1986) ("[I]t is precisely \textit{because} the government could have enacted a wholesale prohibition of the underlying conduct that it is permis-
strengthen the burden the legislatures have in justifying infringing free speech. At issue in City of Cincinnati v. Discovery Network,224 was a city ordinance that refused to allow distribution of magazines that advertised adult educational, recreational, and social programs.225 The city ordinance was prompted by the city’s interest in the safety and attractiveness of streets and sidewalks.226 The Court held that it would not adopt the lowest standard of review possible for evaluating the means and ends of a restriction on commercial speech.227 The Court did, however, consider the availability of numerous less-burdensome alternatives as a relevant factor in the determination of whether a reasonable fit exists between the state’s interests and the means chosen to advance those interests.228 Later, in Rubin v. Coors Brewing Co.,229 the Court decided whether a federal law prohibiting a beer manufacturer from displaying alcohol content on beer labels was constitutional.230 The Court held that the federal law failed the Central Hudson test,231 in part, because of the availability of other alternatives that would advance the government’s interest of preventing beer companies from competing for the strongest beer.232 In fact, the Court noted that the availability of other options indicated that the federal prohibition was more extensive than necessary.233

Many of the restrictions proposed by the Failed Settlement were more extensive than necessary and, most likely, would have failed the fourth prong. The government’s interest of reducing youth smoking, albeit a substantial one, could be achieved by less drastic means that would be less burdensome on free speech. For example, the ban on all outdoor advertising is a complete statutory ban that, most likely, would not survive constitutional scrutiny. In 44 Liquormart,234 the Court invalidated

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225. See id. at 412.
226. See id.
227. See id. at 417 n.13.
228. See id.
230. See id. at 478.
231. See id. at 491.
232. See id. at 490-91.
233. See id. at 491.
the statutory ban on price advertising of alcoholic beverages because the ban was a more extensive suppression than necessary on truthful, non-misleading commercial speech. Although commercial speech, in general, receives less protection from the First Amendment than other types of speech, the Court found the state could not establish a reasonable fit between its interests and the means chosen. There were other alternative forms of regulation that could have achieved the state’s goals.

The Court in *44 Liquormart* enumerated several alternatives that would not restrict commercial speech but would advance the state’s interest in promoting temperance. The Court suggested that the legislature could adopt other methods, such as raising prices, increasing taxes and implementing educational programs, to decrease the consumption of alcohol. It is likely that the Court will look to the identical alternatives espoused in *44 Liquormart* to argue that less burdensome alternatives exist rather than banning all outdoor advertising.

Advertising restrictions must be carefully crafted to confine their focus to those areas of advertising that are most visible to children. For example, prohibiting outdoor advertising within one thousand feet of schools and public playgrounds may be a more practical solution. Or, perhaps, another tailored restriction would be to impose the black-and-white, text-only ban to publications whose teenage readership is close to one hundred percent. These requirements would not deprive consuming adults of the free flow of information. Information about the product may be conveyed to interested consumers through words. Moreover, advertisements with color and imagery would still be permitted to flourish in adult publications and in adult locations.

235. The Court applied the fourth prong of the *Central Hudson* test and determined that Rhode Island could not satisfy the requirement that speech restrictions be no more extensive than is necessary. See *id.* at 507.
236. See *id.*
237. See *id.*
238. See *id.*
239. See *id.*
240. This type of a restriction was suggested by the FDA in its Final Rule on Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. See 61 Fed. Reg. 44396, 44399 (1996).
D. Surviving Constitutional Analysis as a Time, Place and Manner Restriction

Some of the restrictions may survive constitutional analysis as a regulation of time, place, and manner. Generally, restrictions on time, place, or manner do not infringe on an individual’s First Amendment rights and are valid restrictions on speech.²⁴¹ The Supreme Court utilizes a three-part test to evaluate whether a time, place, or manner restriction is valid.²⁴² First, the restriction must be content-neutral in that it restricts speech irrespective of the actual content of the expression.²⁴³ Second, the restriction must be narrowly tailored to serve a substantial governmental interest.²⁴⁴ It must be shown that the substantial government interest will be achieved less effectively without the regulation, and that the means chosen to effectuate the governmental interest are not substantially broader than necessary.²⁴⁵ Finally, the restriction must not block ample, alternative channels for communicating the information.²⁴⁶ Other methods for expressing speech must be left open.

Rather than ban all outside advertising as suggested in the Failed Settlement, a prohibition on outdoor advertising within one thousand feet of schools and playgrounds may be a valid time, place, and manner restriction. Although it may be argued that the restriction is not content-neutral, at least tobacco manufacturers are left with numerous channels to communicate information about their products.

Another suggestion is the requirement originating in the Failed Settlement that advertising exposed to children be in black-text on a white background. A restriction such as this does not prevent tobacco manufacturers from communicating information about their products to adults, but it may be substantially broader than necessary. After all, the

²⁴¹ See NOWAK & ROTUNDA, supra note 160, at 1087.
²⁴³ See id. (“[R]estrictions of this kind [expression subject to time, place, and manner restrictions] are valid provided that they are justified without reference to the content of the regulated speech . . . .”). See generally NOWAK & ROTUNDA, supra note 160, at 1087 (stating that regulations must be content-neutral, “[o]therwise the state would be able to cloak restrictions on speech itself in the guise of regulations of the mode of speech or the place . . . that is used for the speech”).
²⁴⁴ See Clark, 468 U.S. at 293.
²⁴⁵ See Ward, 491 U.S. at 782-83.
²⁴⁶ See Clark, 468 U.S. at 293.
only publications exempted from the restrictions are those whose readership of eighteen years old or younger is fifteen percent or less but no greater than two million people. Publications that have a low percentage of youth readers, but do not meet the conditions to be exempted from the restriction, will have to comply with the black-and-white, text-only advertisement. As a result, the First Amendment rights of adult readers to receive information will be unprotected. In a publication with eighty-percent of its readers older than eighteen, such a measure seems more drastic than necessary.

E. Analyzing Whether the Restrictions are Tools Used by the Government to Favor One Viewpoint Over Another

A restriction that passes the Central Hudson test or qualifies as a valid time, place, and manner restriction, may, nonetheless, be struck down as a viewpoint-based restriction. The government cannot discriminate against an idea or perception because it may be dangerous to its listeners. A certain viewpoint cannot be supported by imposing restrictions on the opposite view. Whatever society’s ideas and perceptions are, they must be developed by a well-informed public and not by the government.

The restrictions suggested in the Failed Settlement may be viewpoint-based restrictions, and as such, deemed unconstitutional. Should similar restrictions be imposed in the future, the government would be suppressing information about tobacco products based on the content of the messages. The federal government would be quashing the idea that smoking is good. However, the opposite message, that smoking is bad, would not be subject to any restriction. To illustrate, if an anti-tobacco entity were to use a cartoon character to inform readers not to use tobacco products, their conduct would not fall within any of the restrictions on advertising. The restrictions in the Failed Settlement were im-

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247. See American Booksellers Ass’n v. Hudnut, 771 F.2d 323, 327 (7th Cir. 1985) aff’d, 475 U.S. 1001 (1986) (“Under the First Amendment, the government must leave to the people the evaluation of ideas.”). At issue in American Booksellers Ass’n was an anti-pornography civil rights ordinance. See id. at 325-26. The ordinance was struck down because it impermissibly discriminated on the basis of point of view. See id. at 323. The court argued that “[o]ne of the things that separates our society from [totalitarian governments] is our absolute right to propogate opinions that the government finds wrong or even hateful.” See id. at 328.
posed on the tobacco manufacturers and distributors, but not on any organization that promotes anti-tobacco messages. While the tobacco manufacturers would be restricted in conveying information about their products to the public, anti-tobacco messages would be communicated irrespective of any encumbrances a settlement may impose. Promoting one viewpoint at the expense of another, through legislation, is precisely what First Amendment case law in the area of viewpoint discrimination was designed to prevent.

IV. GIVING THE FOOD AND DRUG ADMINISTRATION JURISDICTION OVER TOBACCO PRODUCTS AS A MEASURE TO CONTROL TOBACCO USE

A. How the Failed Settlement Proposed to Grant Jurisdiction to the Food and Drug Administration

One of the main features of the Failed Settlement, which sets it apart from past federal legislation, was the provision granting authority to the Food & Drug Administration. Under the Failed Settlement, tobacco products would have been treated as "drug devices" under a separate chapter within the FDA's enabling statute, the Federal Food, Drug, and Cosmetic Act (FDCA). In other words, the FDA would have authority over tobacco by way of a new chapter devoted to regulating tobacco products that would have been inserted in the FDCA.


249. Although the title of section 142 was "Treatment of Tobacco Products as Drugs," section 142 (d) stated that, under the proposed bill, tobacco products were to be classified as a class II device. See id. §§ 142, 142(d); see also infra note 268 (defining "drug device" under the FDCA). A class II device is defined under the FDCA as:

A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, ... development and dissemination of guidelines, ... recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance.


250. See infra Part IV.B.

251. See S. 1415, 105th Cong. § 143 (stating that the FDCA is amended by adding a new chapter entitled "Chapter IX - TOBACCO PRODUCTS").
One purpose in giving the FDA control over tobacco was to promote the development of safer tobacco products by creating a regulatory scheme to reduce the level of certain ingredients, like nicotine.\textsuperscript{252} Tobacco manufacturers would have been subjected to performance standards that would have resulted in a reduction of health risks from the use of tobacco products.\textsuperscript{253} The performance standards would have included provisions forcing manufacturers to change the composition of their products to decrease illness or injury that may be inflicted.\textsuperscript{254} Other provisions that concerned the construction, composition, and ingredients of tobacco products would also have been required.\textsuperscript{255} An advisory committee would have been established, called the “Scientific Advisory Committee,” to assist in the development of proper performance standards.\textsuperscript{256} The members of the advisory committee would have included experts in medicine, science, and other fields that involve the manufacture and use of tobacco products.\textsuperscript{257}

The Failed Settlement also contained a provision encouraging the development of a less hazardous tobacco product.\textsuperscript{258} Should the manufacturing of a safer product be technologically feasible, tobacco manufacturers would have been forced to produce and distribute a less hazardous product.\textsuperscript{259} This section also provided financial grants and other contracts to manufacturers to develop safer products if such financial sup-

\textsuperscript{252} See id. § 143 (referring to section 902 of the chapter that would have been devoted to the regulation of tobacco products under the Failed Settlement).
\textsuperscript{253} See id. § 143(3) (referring to section 905 entitled “Performance Standards for Tobacco Products”).
\textsuperscript{254} See id. (referring to section 905(b)(1)).
\textsuperscript{255} See id. (referring to section 905(b)(2)).
\textsuperscript{256} See S. 1415, 105th Cong. § 143 (referring to section 906(a), which addressed the establishment of a Scientific Advisory Committee).
\textsuperscript{257} See id. (referring to section 906(b), which addressed how the Scientific Advisory Committee would be staffed).
\textsuperscript{258} See id. (referring to section 908 entitled “Reduced Risk Products”).
\textsuperscript{259} See id. (referring to section 908(d)(2) and specifying that the Commissioner of the FDA would determine that a less hazardous product is technologically feasible). According to the Failed Settlement, a manufacturer would have been able to elect not to manufacture the less hazardous product at the demand of the FDA Commissioner. See id. (referring to section 908(d)(3)(B)). The manufacturer had to provide notice to the Commission and the manufacturer had to provide the technology at a reasonable price so the less hazardous product could be manufactured. See id. (referring to section 908(d)(3)(B)).
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port were necessary. The Industry would have been compelled to disclose a list of the ingredients contained in their products.261 At a minimum, tobacco packaging would have contained a list of all the contents of the ingredients so that the public would be made aware of the product’s contents.262 It was also required that within five years of the Failed Settlement’s enactment, each manufacturer would submit a safety assessment for each ingredient based on scientific evidence.263 If any ingredient was disapproved, it would have been prohibited by the FDA in the manufacturing process.264

B. What is the FDA?

The Federal Food, Drug, and Cosmetic Act265 was enacted in 1938 as the enabling statute creating the Food & Drug Administration.266 The FDCA defines the scope of power the FDA has over drugs267 and drug delivery devices.268 Through the FDCA, the FDA regulates the distribu-

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260. See id. (referring to section 908(d)(4)).
261. See S. 1415, 105th Cong. § 143 (referring to section 910 entitled “Disclosure and Reporting of Nontobacco Ingredients”).
262. See id. (referring to sections 910(a)(1)(A), (B) and noting that the list would have included everything that is added to the tobacco as well as a description of the quantity of each ingredient, substance or compound that comprise the list).
263. See id. (referring to sections 910(b)(1), (2)).
264. See id. (referring to section 910 (c) (1) (B)).
266. An enabling statute is the statute from which an administrative agency gets its powers. See BLACK’S LAW DICTIONARY 526 (6th ed. 1990); see also 21 U.S.C. § 371 (a) (1994) (granting the power to the FDA to “promulgate regulations for the efficient enforcement of this chapter”).
267. See 21 U.S.C. § 321 (g)(1). The FDCA defines drugs as:
   (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A). (B), or (C).
268. See 21 U.S.C. § 321(h). The FDCA defines device as:
   [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is recognized in the offi-
tion and manufacturing of drugs and drug delivery devices by examining and approving new drugs defining specific products as drugs and imposing civil and criminal penalties for violations of the FDCA.

C. Is Congress the Only Governmental Body Permitted to Grant Jurisdiction to the FDA, or Can the FDA Exert its Own Jurisdiction?

Although Congress has never conferred authority to the FDA over tobacco products, the FDA, as well, has consistently maintained that it did not have jurisdiction over tobacco products. According to the FDCA, the FDA has authority over drugs or devices if they are manu-

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270. See id. § 321.
271. See id.
272. See generally supra Part I (describing federal legislation enacted by Congress directed towards tobacco products).
273. See Action on Smoking and Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980). Action on Smoking and Health (ASH) filed a petition with the FDA requesting that the Agency assert jurisdiction over cigarettes. See id. at 237. ASH alleged that cigarettes fall within the FDA's jurisdiction because cigarettes are articles other than food intended to affect the structure or a function of the body. See id. (quoting the pertinent part of the definition of "drug" that ASH believes cigarettes fall under, 21 U.S.C. § 321(g)(1)(C) (1976)). Because the FDA refused to deem cigarettes a drug unless specific health claims were made by the manufacturers or distributors, the FDA Commissioner, Donald Kennedy, rejected ASH's request. See id. The FDA Commissioner noted that ASH presented no evidence to show that the manufacturers or vendors of cigarettes intended to affect the structure or a function of the body. See id. at 239. Dr. Charles C. Edwards testified at a Senate Hearing in which he stated that "cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug, and Cosmetic Act." Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before the Consumer Subcommittee of the Senate Comm. on Commerce, 92nd Congress, 2d Session 239 (1972).
factured with the intent to affect the function or structure of the body.°°

Intent to manufacture a product that fits under this definition of "drug" or "device" may be proven by subjective claims made by cigarette vendors, or objective evidence such as contents of the labeling, promotional materials, or advertising.°° As a result, in the past the Agency would only intervene when manufacturers made express health claims about their products.°° Without such evidence, the FDA was unwilling to exert its control.

The trend changed in August 1995, when the FDA issued regulations governing the access and promotion of tobacco products.°° In general, the regulations restricted the sale and distribution of tobacco products.°°


°°° "Clearly, it is well-established 'that the 'intended use' of a product is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant sources.' Action on Smoking and Health, 655 F.2d at 239 (quoting Hanson v. United States, 417 F. Supp. 30, 35 (D. Minn.), aff'd, 540 F.2d 947 (8th Cir. 1976); see also United States v. 46 Cartons, more or less, containing Fairfax Cigarettes, 113 F. Supp. 336, 338 (D.C.N.J. 1953) (stating that "[t]he manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put."); United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 849-50 (D.C.N.J. 1959) (establishing that the cigarettes fell under the FDA's drug jurisdiction by looking at, inter alia, the label on the packaging, the directions on the packaging, display cards used for advertising, television, and radio commercials).

°°°° United States v. 46 Cartons, more or less, containing Fairfax Cigarettes, 113 F. Supp. 336 (D.C.N.J. 1953), involved the dissemination of leaflets that suggested that the cigarettes accompanying the leaflets were effective at preventing respiratory diseases and other diseases, like pneumonia, influenza, and tuberculosis. See id. at 337. It was held that the tobacco products were "drugs" as defined under the FDA and, as such, could be seized by the FDA. See id. at 339. Although the court acknowledged that the manufacturer may not have believed it was selling drugs, the leaflet gives the public the idea that the cigarettes could be used for the prevention of certain illnesses. See id. at 338. The court determined this was enough to bring it within the definition of "drug" as espoused in the FDCA. See id. at 239. In United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.C.N.J. 1959), the cigarettes were marketed as products to reduce appetite. See id. at 849-50. Since the Trim cigarette was intended to affect the structure and functions of the human body by reducing the appetites of its consumers, the court determined that the products came under the FDA's jurisdiction under the FDCA's definition of "drug." See id. at 851.


°°°°°° See id. at 44399 (outlining the provisions of the regulations restricting sale and distribution of cigarettes).
Predicated on the FDA’s jurisdiction to control cigarettes and smokeless tobacco as drug devices,779 the FDA determined that the nicotine in tobacco products affects the structure or function of the body.280 This indicates that nicotine causes and sustains addiction while acting as a stimulant, sedative, and weight reducer.281

Although the FDA recognized tobacco as the leading cause of preventable death among Americans,282 it was concerned that millions of people are addicted to tobacco products that have been legally on the market for years.283 Based on this concern, the FDA concluded that the best course of action would not be to focus primarily on curbing the habits of those already addicted. Rather, the FDA’s purpose should be to minimize the number of people that become addicted.284 Because most smokers in the U.S. began using tobacco before the age of eighteen, the FDA focused its regulations and restrictions on children.285

Some of the restrictions the FDA promulgated include: (1) requiring retailers to verify that purchasers are at least eighteen years of age,286 (2) restricting the sale of cigarettes from vending machines,287 (3) restricting tobacco companies from selling or distributing promotional items, such as tee-shirts and baseball caps, that have a logo or other identifiers of tobacco products,288 (4) requiring that advertising visible to children be on black-and-white, text-only format,289 and (5) prohibiting billboards and other outdoor advertising within one thousand feet of schools and playgrounds.290

Regardless of whether a settlement is enacted into law, Congress has the power to grant explicit control over tobacco products to the FDA.291

279. See id. at 44396-97.
280. See id. at 44397 (concluding that “[c]igarettes and smokeless tobacco are combination products consisting of the drug nicotine and device components intended to deliver nicotine to the body.”).
281. See id.
282. See id. at 44398.
284. See id. at 44398-99.
285. See id. at 44399.
286. See id.
287. See id. (stating that this restriction does not apply in facilities where individuals under eighteen are not permitted at any time).
289. See id.
290. See id.
291. See U.S. CONST. art. I, § 8, cl. 3. (granting to Congress the power to
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Congress could enact legislation that would allow the FDA to regulate without the Industry’s approval. Although Congress did not express its intent to have the FDA control tobacco products,292 it may be the only governmental body with the vested authority to do so. The FDA’s authority to exert its own jurisdiction was challenged in Brown & Williamson Tobacco Corp. v. Food & Drug Administration,293 and the outcome was not promising for the Agency.294 The Fourth Circuit addressed whether the FDA could regulate tobacco products based upon its own interpretation of the FDCA. In opposing the regulations, tobacco manufacturers, retailers, and advertisers argued that the FDA does not have jurisdiction over tobacco products.295 They alleged that (1) Congress withheld jurisdiction from the FDA, and (2) the FDCA does not permit the FDA to regulate tobacco products as either drugs or drug-delivery devices.296 The FDA argued that it has authority to regulate tobacco products because tobacco products fit within the literal definitions of “drugs” and “devices” as defined in the FDCA.297 Because the FDA is responsible for regulating “drugs” and “devices,” it would be reasonable to conclude that it would have authority over tobacco products.298 The court agreed that tobacco products may fit under the literal definitions of “drug” and “drug-delivery device.”299 However, the Fourth Circuit held that Congress did not intend for tobacco products to come within the FDCA’s definition of “drug” or “device.”300 The literal definitions must be examined by looking at the language of the FDCA as well as the

292. See supra Part I.
293. See 153 F.3d 155 (4th Cir. 1998).
295. See Brown & Williamson, 153 F.3d at 159.
296. See id.
297. See id. at 160 (outlining the FDA’s argument for asserting jurisdiction over tobacco as evinced in the Final Rule published in the Federal Register, 61 Fed. Reg. 44396. (1996)).
298. See id.
299. See Brown & Williamson, 153 F.3d at 163 (“A mechanical reading of only the definitions provisions may appear to support the government’s position that tobacco products fit within the Act’s [FDCA] definitions of drugs or devices.”).
300. See id.
structure of the Act as a whole. The court inferred that Congress did not intend for the FDA to regulate tobacco because tobacco products could not meet the conditions of safety and effectiveness that are mandated by the FDCA. Moreover, the fact that Congress did not enact legislation that would have granted jurisdiction to the FDA, but did enact bills giving other agencies the authority to regulate specific areas in tobacco manufacturing and distribution, was significant in deciding that the FDA exceeded its authority.

D. Is Giving the FDA Jurisdiction Over Tobacco Products a Wise Decision?

Giving the FDA jurisdiction over tobacco products would be one of the best measures to regulate the Industry and tobacco products. There are many reasons why giving the FDA authority to regulate tobacco products is a good measure to control tobacco use. First of all, the FDA will be prepared to effectuate Congress' goal of developing a regulatory scheme that focuses on the manufacturing and distribution of tobacco products. The FDA issued its Final Rule which specifically focuses on regulating the manufacturing and distribution of tobacco products. Yet, it was not announced until the FDA considered numerous responses and comments from the public on the subject of regulating tobacco. Several issues and concerns presented from the public were evaluated, addressed, and examined thoroughly in its published analysis for the Final Rule. Such an exhaustive exposition of the issues involved indicates that the FDA is prepared to handle the complex task of regulating

301. See id.
302. See id. at 166-67.
303. See id. at 170-71.
304. See S. 1415, 105th Cong § 143 (1997) (referring to section 902 which would have been implemented in the Failed Settlement bill if enacted).
306. See, e.g., 61 Fed. Reg. at 44420. “Some comments suggested that if the Government begins regulating tobacco, it will soon regulate many other consumer products that are now legal, but judged to be harmful to health, including alcohol and caffeine.” Id. “Many comments ... argued that the tobacco industry is already intensely regulated, and that more regulation is unneeded and unjustified.” Id. “[A] section ... of this document provides responses to questions raised about the constitutionality of the regulations.” Id. at 44466. “FDA received thousands of comments about how smoking was an issue of free choice for adults.” Id. at 44418.
tobacco. The Agency is aware of the public's concerns surrounding the regulation of tobacco, and it will, more than likely, incorporate the public's concerns in whatever regulations it imposes.

A second reason why giving the FDA authority to regulate tobacco would be a wise decision is because the Agency would exercise good judgment in effectuating the goal of decreasing tobacco use without abusing its discretion. Although it would be premature to predict that the Agency would implement the provisions from the Final Rule should it be given authority over tobacco, they serve, nonetheless, as a good indicator of the FDA's motives. The provisions in the Final Rule were specific and detailed. Instead of restricting the sale of tobacco products to the general public, for example, the FDA wanted to simply restrict the sale of tobacco products to children. The FDA confined its own authority to a limited scope by focusing on children as opposed to exerting authority through broad, overreaching provisions that may infringe harshly on the rights of adult smokers. Although the power to regulate an industry as powerful as the tobacco industry is a great amount of authority allocated to one agency, the FDA is aware of its limitations and its goals.

Despite the encouraging potential for a decrease in the amount of tobacco use in the United States should the FDA receive authority over tobacco, there are two concerns that this grant of authority may raise.

1. The First Concern: Will Granting Jurisdiction to the FDA Overreach its Boundaries?

The purpose behind the creation of the FDA may be frustrated if it is given authority to regulate tobacco products. Under the FDCA, all drugs and drug-delivery devices marketed to the public have to be safe and effective for use. In fact, FDA Deputy Commissioner William B. Schultz stated that a fundamental principle of drug and device regulation is that all drugs and devices are proven safe and effective before they are

307. See supra Part IV.C.
308. See id.
309. See 61 Fed. Reg. at 44398 ("In determining the best course of action, the Agency considered the highly addictive nature of cigarettes and smokeless tobacco and the fact that these products have previously been lawfully marketed to millions of adult Americans.")
310. See 21 U.S.C. § 355 (1994) (requiring new drugs to meet conditions of safety and efficacy); id. § 360c(a)(2) (requiring devices to meet conditions of safety and efficacy).
yet, the FDA states that tobacco products are dangerous and unsafe. 312 There are no health benefits achieved by using tobacco products, and more than 400,000 people each year die as a result of tobacco use. 313

Despite the FDA's findings on the dangers of tobacco use, a ban on tobacco products has never been promoted. The FDA adamantly argued in its Final Rule that a complete ban on tobacco products is not a measure that would best serve the public interest. 314 Proper medical treatment is not currently available to care for the millions of smokers experiencing withdrawal if a ban were enacted. 315 The FDA also recognized that a black market could emerge and force a stronger, more dangerous tobacco product to be manufactured. 316 Furthermore, the FDA found that prohibition is unnecessary because the imposed regulations will inhibit the spread of smoking behavior from one generation to the next. 317 As current smokers die or quit, they will be replaced by fewer new smokers. 318

The refusal by Congress and the FDA to propose a ban on tobacco products directly conflicts with the FDCA and the purposes of the FDA. Because cigarettes and smokeless tobacco, as they are currently marketed, are unsafe, they would be deemed unapproved new drug devices if marketed. Congress may need to exempt tobacco products from the safe and effective condition if it chooses to give the FDA jurisdiction. Although doing so would frustrate a fundamental principle of the FDA, it would be far more detrimental if the FDA were forced to impose a ban on tobacco products.

2. The Second Concern: Providing for the Development of a Less Hazardous Product

The drafters of the Failed Settlement devoted an entire subsection to discussing how the development of a safer tobacco product will be

313. See id.
314. See id. at 44418-19.
315. See id. at 44398.
316. See id.
318. See id.
regulated.\textsuperscript{319} There remains, however, little incentive for the tobacco companies to develop a safer product on their own initiative. Although tobacco manufacturers may be required to produce a less hazardous product, they ultimately have the choice of whether or not to actually modify and market the product.\textsuperscript{320} Provided a manufacturer gives adequate notice to the FDA and agrees to make the technology available at a reasonable price, the manufacturer may exercise its own discretion in determining whether to develop the less hazardous product.\textsuperscript{321} Furthermore, the Failed Settlement did not posit any regulation forcing the Industry to research and test for a less hazardous product, nor did it suggest any possibility that the FDA, itself, would adopt a mechanism for the creation of a safer product.\textsuperscript{322}

Although tobacco manufacturers may be in the best position to know how to develop a safer product, allowing the manufacturers the option of not creating a less hazardous product calls for the FDA to rely completely on manufacturers to develop a safer cigarette. Such a policy is ludicrous because it assumes that the tobacco industry will be honest and forthcoming in disclosing information about new technology. This is not a realistic expectation when the tobacco industry has been deceptive in the past.\textsuperscript{323} To prevent history repeating itself, the government should be wary of leaving it to the discretion of the Industry to disclose information about its activities and manufacturing processes. The Industry may not want to manufacture a safer product out of its desire to maintain the demand for its products as they are currently manufactured. Moreover, evidence that a safer cigarette may be manufactured could be used against the Industry in subsequent tort litigation.\textsuperscript{324} Developing a safer product may cause a jury to infer that traditional cigarettes were negligently manufactured, and as a result, the tobacco industry will be liable.

\begin{itemize}
\item \textsuperscript{319} See supra Part IV.A.
\item \textsuperscript{320} See id.
\item \textsuperscript{321} See id.
\item \textsuperscript{322} See id.
\item \textsuperscript{323} See supra Part II.D.3 (referring to the tobacco industry's awareness of the addictive nature of cigarettes and its attempts to conceal it from the public, as well as the tobacco industry's interest in children when evaluating marketing strategies).
\item \textsuperscript{324} See Hanson & Logue, supra note 51, at 1340.
\end{itemize}
V. SUMMATION

Legislation, whether through a settlement between the Industry and Congress or by Congress acting on its own accord, needs to be implemented to control tobacco use in the United States. This Comment analyzed three significant measures that were contemplated by members of the Industry and Congress during negotiations over the Failed Settlement. Each measure would be effective, to some degree, at controlling tobacco use. However, the best measure is giving the FDA jurisdiction to regulate the manufacturing and distribution of tobacco products.

The primary reason FDA regulation is the best measure to adopt is because the other two measures, the grant of immunity and advertising restrictions, are unworkable solutions. Granting the Industry immunity will only permit it to avoid paying millions of dollars in restitution to individuals that suffer from tobacco-induced diseases. The success of future lawsuits is promising, especially in light of the documents that have been released detailing the Industry’s attempts to attract and addict smokers. Should the Industry refuse to settle without an immunity provision given to them, then Congress should forego any settlement negotiations with the Industry, and simply legislate measures to control tobacco.

Congress should not use restrictions on advertising as the primary method of legislation. The analysis of the restrictions contained in the Failed Settlement demonstrates that any ban or prohibition must go through exhaustive constitutional review. Congress could promulgate limited, narrowly tailored restrictions, such as a ban on billboards within one thousand feet of schools or black-and-white, text-only in publications that have greater-than-majority readership of teenagers. Yet, even these measures may not withstand constitutional scrutiny under the fourth prong of a First Amendment analysis under Central Hudson. Even assuming, arguendo, that any advertising restriction would pass constitutional muster under Central Hudson, it may be deemed unconstitutional as an invalid time, place, and manner restriction or fail as a restriction based on viewpoint discrimination.

Instead, the primary channel of regulations should come from the FDA, and Congress should not hesitate to grant authority to control to-

325. See supra Parts II, III, IV.
326. See supra Part II.D.4.
327. See supra Part II.D.3.
328. See supra Part III.
bacco to the FDA. As analyzed in this Comment, the proposals that gave the FDA authority to regulate tobacco under the Failed Settlement should be effective.\textsuperscript{329} The measures are geared toward developing a less-hazardous product, and they demand that the tobacco manufacturers be held to strict performance standards.\textsuperscript{330} Manufacturers would be made to reveal the contents of their products, and a Scientific Advisory Committee would be created as an advisor to the FDA.\textsuperscript{331}

The tobacco manufacturers would be forced to work with the government through the FDA. This would be an unprecedented measure for an industry that was uncontrolled to a great extent by the government for years.\textsuperscript{332} It may be the only workable alternative available, and it may be the only one this country needs.

CONCLUSION

Tobacco use is a serious threat to the public health, and measures controlling its use must be implemented to decrease the incidence of tobacco-related death and disease. Although legislation controlling tobacco has been implemented since the mid-1960s, it has been largely ineffective. After all, death from tobacco use still remains the single-leading cause of preventable death in this country today.

Measures similar to those pronounced in this Comment will have a significant effect on the level of death and disease from tobacco use. Regardless of whether the Industry settles with the federal government, each measure described in this Comment will significantly alter the way tobacco companies manufacture and distribute their products. Some measures will be more effective than others. Yet, at a minimum, this Comment encourages future discussions on the issue of controlling tobacco use in the efforts of significantly decreasing the amount of deaths from tobacco-induced diseases.

EPILOGUE

At the publication of this Comment, four of the biggest tobacco manufacturers, Philip Morris, R.J. Reynolds, Brown & Williamson, and Lorillard settled with forty-six states that initiated suits to recover Medicaid

\textsuperscript{329} See supra Part IV.
\textsuperscript{330} See supra Part IV.A.
\textsuperscript{331} See id.
\textsuperscript{332} See supra Part I.
costs related to smoking. The deal includes a $206 billion payout over the next twenty-five years and ends one of the biggest legal challenges that faced the Industry. This new settlement is only a first step, however, in the fight to control tobacco use in this country. The settlement is solely concerned with resolving the state-initiated suits. It does not involve implementing any federal legislation designed to control tobacco. It does not include giving jurisdiction to regulate tobacco products to the FDA, nor does it provide immunity to the manufacturers against other pending suits. Restrictions on advertising are imposed, however, any such restriction still needs to pass constitutional muster to be effective against the Industry. The tobacco manufacturers may accede to restricting their advertising, yet, a waiver of this sort does not preclude the tobacco consuming public from asserting a violation of the First Amendment.

Any negotiation the government has with members of the Industry is a hopeful and encouraging venture. It is crucial, however, that the government realize that it cannot stop there. Whatever monetary settlement members of the Industry propose to the states, collectively or individually, should not obstruct the vision of the federal government in continuing the move toward adopting measures to effectively control the use of tobacco.

Christina F. Pinto

335. See id. at A7.
336. See id. at A1.