Big Tobacco: An Impenetrable Industry Regulators Can Only Hope to Contain

"'Old Joe, that hip cartoon camel . . . is now as familiar to young children as Mickey Mouse, and apparently . . . entic[es] thousands of teens to smoke that brand.' . . . Teenage smokers accounted for about $476 million of Camel sales in 1992 as compared with $6 million in 1988 at the onset of the Old Joe Camel advertisements. . . . Given that it is illegal to sell or furnish cigarettes to persons under the age of eighteen years and it is unlawful for minors to purchase or receive cigarettes, the targeting of minors in cigarette advertising offends public policy. "Cigarette advertising directed to minors contravenes the statutory policy of keeping children from starting on the road to tobacco addiction. . . . [L]eaving aside the subjective questions of morals and ethics, the targeting of minors is oppressive and unscrupulous, in that it exploits minors by luring them into an unhealthy and potentially life-threatening addiction before they achieved the maturity necessary to make an informed decision whether to take up smoking despite its health risks."  

This note discusses current issues involving tobacco regulation. First, the note briefly addresses the problems associated with tobacco use and indicates that the roots of these dangers begin in childhood. Part II of the note overviews the general history of tobacco regulation and provides a framework for the Federal Food and Drug Administration's (FDA) basis for jurisdiction over tobacco products. Next, part III outlines three major justifications for the regulation of tobacco products. After noting a recent court decision which provided the FDA statutory authority to regulate tobacco, part IV discusses the settlement between the tobacco industry and forty state attorneys general which circumvents the thrust of the ruling. Finally, the note concludes that in light of the perils of tobacco use, the settlement marks a retreat in the war against "Big Tobacco."

1. Mangini v. R.J. Reynolds, 875 P.2d 73, 75-76 (Cal. 1994). The dissemination of products such as matchbooks, store exit signs, scrip, mugs, and soft drink can holders advertising Camel cigarettes has been extremely effective in targeting adolescents. Id. at 75. Sources suggest that the percentage of teenage Camel smokers increased from 0.5 percent in 1988 to between 25 and 33 percent in 1992. See id. (suggesting aggressive advertising increased Camel's popularity 66-fold).

I. INTRODUCTION

The combined number of deaths attributable to AIDS, illegal drugs, car accidents, alcohol, homicides, suicides, and fires, fails to overshadow the total deaths caused by cigarette smoking alone. With an annual death toll of over 400,000 Americans, "cigarette smoking is the number-one preventable cause of death and disease in the United States." By causing 1200 deaths a day and 50 deaths each hour, tobacco serves as the plague of our time. Given these statistics, the tobacco industry provides a clear case for social regulation.

Although resulting disease and death do not strike until adulthood, the smoking epidemic begins in childhood. Eighty-two percent of all adults smokers started smoking before their eighteenth birthday. Children are extremely vulnerable to provocative cigarette advertising because of their inability to maturely assess the risks associated with tobacco consump-

3. Kathiann M. Kowalski, Taking Aim at Teen Smoking, CURRENT HEALTH 2, March 1, 1996, at 13. Moreover, the number of annual smoking related deaths is greater than six times the number of Americans killed during the Vietnam War. See James W. Henges, Cigarettes: Defectively Designed or Just Extremely Dangerous?, 18 OKL. CITY U. L. REV. 559, 559 (1993) (placing number of annual smoking related deaths into perspective).


7. See David A. Kessler, The War on Tobacco: Teens are Lured into Lifelong Addiction, SAN DIEGO UNION & TRIB., August 20, 1995, at G1 (noting nicotine addiction typically begins during adolescence). The most recent Surgeon General’s report noted that although smoking among adults is declining, tobacco use among children is growing. See Dr. Elizabeth Whelan, Children and Tobacco Don’t Mix, COM. APPEAL, (Memphis), March 27, 1994, at B3. Every day, 3000 adolescents become regular smokers. See Kessler, supra at G1; see also Kowalski, supra note 3, at 13 (noting 3000 teens per day start smoking). One out of every three of these children will eventually die from a tobacco-related disease. See Kowalski, supra note 3, at 13.

8. See Kowalski, supra note 3, at 13 (displaying young average age of beginner smokers). In 1994, studies showed that nearly 19 percent of eighth graders and 31 percent of twelfth graders had become smokers. Id. Three million minors consume an estimated 947 million packs of cigarettes per year, despite laws prohibiting such sales. Whelan, supra note 7, at B3. Consequently, these illegal sales result in an approximate $221 million gain to the industry. Id.
tion. Despite awareness of the dangers inherent in smoking, many young children often make a casual decision to use tobacco, believing that the risks do not apply to them. Essentially, the epidemic is a pediatric disease, and unless the system changes, 3000 children per day will continue to become smokers.

On August 10, 1995, President Clinton recognized the gravity of the tobacco epidemic and called for new regulations to reduce teen smoking. The following day, the FDA proposed new regulations gov-

9. See Arno, supra note 6, at 1258 (justifying social regulation of tobacco industry due to impact on vulnerable populations). Government has long held the constitutional authority to protect children and adolescents through its parens patriae powers. Id. Although individuals can choose whether or not to smoke, the argument for voluntary choice disappears when dealing with a minor incapable of exercising the proper choices permitted by law. Id.; see also Whelan, supra note 7, at B3 (suggesting protection of children as first priority of nation’s health policy). Safeguarding America’s youth from tobacco addiction has proved a particularly important governmental priority, and every administration since the 1960’s has singled out cigarette smoking as the most preventable source of death and disease. see id.; supra note 4 and accompanying text (qualifying cigarette smoking as most preventable cause of disease and death).

10. See Kessler, supra note 7, at G1 (emphasizing children’s vast underestimation of tobacco’s power). Children do not experience the consequences of smoking, therefore they perceive these illnesses and diseases as nothing more than rumors. Id. Studies indicate that only a small percentage of children believe that tobacco consumption poses any threat. Whelan, supra note 7, at B3; see also Don Colburn, Rise in Teen Smoking Has Experts Vexed; Few Start Habit After Age 20, Leading FDA Chief to Labeling it a ‘Pediatric Disease’, WASH. POST, September 10, 1996, at Z07 (indicating decreased percentage of students realizing smoking poses serious health dangers). In a recent survey given to eighth-graders, only one half of them thought smoking half a pack a day posed significant health risks. Id. Accordingly, the survey demonstrates teenagers today know less about nicotine than children of earlier generations. Id.

11. See Kessler, supra note 7, at G1 (characterizing smoking as “pediatric disease” because of origins in childhood). Studies demonstrate that if children do not start smoking by age 18 or 19, they will most likely never smoke. Id.

12. See Statement by George Dessart, Chairman of the American Cancer Society, Release of Final FDA Regulations on Tobacco, August 23, 1996, (recognizing Clinton’s bold step toward restricting sales and marketing of tobacco to minors); Sonya Ross, ASSOCIATED PRESS, White House Begins Final Review of Rules to Curb Teen Smoking, August 13, 1996 (observing number of youngsters picking up habit too early); Kowalski, supra note 3, at 13 (stating Clinton directed FDA to establish rules to prevent tobacco from reaching minors); see also CBS This Morning, NewsCast: Dr. David Kessler, FDA Commissioner, Discusses President Clinton’s Plan to Draft Regulations to Prevent Teen-age Smoking (CBS television broadcast, August 11, 1995) (noting Clinton’s unprecedented move declaring nicotine addictive drug); Bill Clinton and Donna Shalala, Remarks to Advocates of Stopping Tobacco Use by Children and Adolescents (March 20, 1996) in FED. NEWS SERV. WASH. PACKAGE (ranking Clinton’s proposal among boldest public health proposals ever). The Coalition on Smoking or Health called the regulations the “most important health initiative ever put forward by a president and his administration affecting children.” Sonya Ross, supra; see also Associated Press, COURIER-J., (Louisville), August 8, 1996, at 03E (ranking FDA regulation plan among nation’s greatest public health achievements).

As President Clinton suggested, the initiative comes at a very good time considering the dangers of tobacco consumption and the rising rate of teen smoking. See Dessart, supra (revealing 26 percent increase in teen smoking since 1991); see also Arno, supra note 6, at 1258 (recognizing evidence that suggests marked increase in smoking among adolescents); Colburn, supra note 10, at Z07 (stating decline in smoking rate “bottomed out” and “stalled” after mid-1980’s). After nearly two decades signal-
ering the sale and distribution of nicotine-containing cigarettes and smokeless tobacco products to children and adolescents. The regulations' central focus on children and adolescents reflects that nicotine addiction typically begins during early adolescence. The proposed rule would reduce minors' easy access to tobacco products as well as decrease the amount of seductive imagery that makes tobacco products so appealing to children. Moreover, the regulations further the FDA's primary objective of reducing death and disease caused by tobacco products.

II. OVERVIEW OF TOBACCO REGULATION

Despite the overwhelming evidence indicating the perils of tobacco consumption, Congress prefers to regulate rather than ban cigarettes.

13. See Proposed Regulations, supra note 4, at 41,314 (providing overall goal of addressing serious health concerns arising from tobacco consumption and addiction).

14. See supra note 11 and accompanying text (discussing young age of smokers). More than three fourths of smokers begin the habit before age 18. See id. (detailing use of tobacco by minors). Nicotine addiction significantly contributes to the continuation of tobacco use. See infra notes 52-59 (discussing nicotine addiction).

15. See Proposed Regulations, supra note 4, at 41,314. Millions of children and adolescents can easily obtain cigarettes and smokeless tobacco. Id. at 41,315. Ease of access raises concern given tobacco consumption by persons under the age of 18 is unlawful. See supra note 8 and accompanying text (discussing illegality of tobacco consumption by minors). Along with easy access to tobacco, advertising and promotional activities influence a minor's decision whether or not to use a tobacco product. Proposed Rules at 41,315. For example, advertisements and promotions convey images of adventure, recreation, romance, and eroticism. See Arno, supra note 6, at 1258 (describing luring effect of tobacco advertising). With a $6 billion-a-year advertising and promotional budget, the tobacco industry can be highly influential by "telling people what's cool." See Colburn, supra note 10, at Z07 (discussing impact of advertising that targets children); see also Kowalski supra note 3, at 13 (highlighting advertisements' display of potential for experiencing good times); Lauran Neergaard: The Associated Press: Tobacco Law Burns Joe Camel: Advertising Restrictions are at the Heart of Effort to Cut in Half the Number of Teens who Smoke, ORANGE COUNTY REG. August 24, 1996, at A01 (suggesting advertisements portray themes of fun, glamour, and independence); Whelan supra note 7 at B3 (associating advertising with glamour and trendiness). The proposed rule would not restrict adult access or use of tobacco products. See Proposed Regulations, supra note 4, at 41,314.

16. See Proposed Regulations, supra note 4, at 41,314 (revealing primary focus of proposed rule).

Over the years, Congress has passed legislation, however, smoking critics have always questioned the regulations' substantiality. In support of the case for insubstantial regulation, anti-smoking proponents note that no federal agency traditionally dealing with health and safety directly authorizes cigarettes, and federal laws dealing with health and safety specifically exempt cigarettes from regulation. Although the government of the United States may have extreme power and influence, no uniform federal anti-smoking regulation currently exists. Consequently, the country is laden with inconsistent state, local, and municipal regulations that often prove ineffective.

The need for implementation of a comprehensive control system continues to grow as the current system becomes increasingly ineffective. In respect to relationships between smoking and health. Id. at § 1331. Cigarette packages must also contain warning notices which adequately inform potential consumers about any adverse effects of cigarette smoking. Id.

18. See Carchman, supra note 17, at 91 (noting disagreement between industry and anti-smoking proponents concerning level of current regulation). Smoking critics attribute the lack of regulation to the power of the tobacco lobby. See Lawrence O. Gostin, FDA Regulation of Tobacco Advertising and Youth Smoking: Historical, Social, and Constitutional Perspectives, 277 JAMA 410, 411 (1997) (attributing exclusion of significant tobacco legislation to tobacco lobbying). To centralize public relations and lobbying efforts, six major tobacco companies formed the Tobacco Institute. See Matthew Baldini, The Cigarette Battle: Anti-Smoking Proponents Go for the Knockout, 26 SETON HALL L. REV. 348, 365 (1995) (discussing impact of tobacco lobbying). This coalition has afforded the tobacco industry significant leverage in attempts to control potential government restrictions. Id. In addition, a unified Congress will most likely not support restrictive tobacco legislation due to the tobacco industry's contributions to political campaigns. See id. at 365 (discussing influence of tobacco lobbying).

19. See Carchman, supra note 17, at 92 (showing limited federal control and regulation over tobacco). In contrast, smoking proponents point to numerous regulations that cover tobacco cultivation and harvesting, packaging, labeling, advertising, and distribution. Id. In addition, the industry "pays stiff taxes, allocates funds for anti-smoking programs, and provides incentives for states to fund anti-smoking programs." Id.


21. See Baldini, supra note 18, at 358. Commentators noting the lack of consistency suggest that lawmakers base the establishment of a uniform system on the premise that nonsmokers have a legal right to enjoy the atmosphere everywhere the law forbids smoking. See id. n.55 (suggesting legislation focus on rights of nonsmoker). By emphasizing the rights of nonsmokers, this type of legislation would place the burden on smokers to determine where they may legally smoke. Id.

22. See id. at 358-59 (commenting on mere results of limited and indirect regulatory measures). But see Donald W. Garner, Banning Tobacco Billboards: The Case for Municipal Action, 275 JAMA 1263, 1263 (1996) available in 1996 WL 10487836 (discussing legality and success of local ordinances restricting cigarette advertising on billboards). In one successful study, a town drafted tobacco legislation along the lines of liquor control laws which required merchants to obtain sales licenses. See generally Leonard A. Jason, Active Enforcement of Cigarette Control Laws in the Prevention of Ciga-
recognition of this need, tobacco foes have urged Congress to pass legislation to rectify the problem. Because the Federal Food, Drug, and Cosmetics Act (FDCA or the Act) does not expressly exempt cigarettes from regulation, many anti-smoking advocates suggest that the Food and Drug Administration (FDA) is best equipped to regulate tobacco products.

A. The FDA

The FDA regulates the nation's food and drug supply. The FDCA gives the FDA jurisdiction to regulate food, drugs, cosmetics, and medical devices. The FDCA's purpose, and in turn the responsibility of the FDA, is to protect the public from the dangers of unsafe and ineffective drugs. Although tobacco consumption poses serious health risks, the FDCA does not provide express regulatory authority over cigarettes.

23. See Reynolds, supra note 20, at 447 (proffering federal legislation as solution to lack of uniformity).

24. See James T. O'Reilly, A Consistent Ethic of Safety Regulation: The Case for Improving Regulation of Tobacco Products, 3 ADMIN. L.J. 215, 233 (1989) (calling FDA most equipped among federal agencies to control nicotine products); see also Carchman, supra note 17, at 93 (showing smoking critics' rationale for FDCA control over manufacturing, labeling, advertising, promotion, and sales). Seventy-five national health, medical, consumer, and religious organizations sponsor a National Petition Drive that supports tobacco regulation under the jurisdiction of the FDA. See id. n.63. But see Carchman, supra note 17, at 114-15 (stating agencies may not base jurisdiction on absence of jurisdiction in other agencies).


26. See Boeckman, supra note 25, 991-92 (defining relation between FDA and FDCA). The FDCA provides the scope of the FDA's drug and device jurisdiction and directs the FDA to ensure the reasonable safety and effectiveness of drugs and devices. Id. at 997. The Act primarily functions to the economic interests of consumers. See United States v. Article ... Sudden Change, 409 F.2d 734, 740 (2d Cir. 1980).

27. See United States v. An Article of Drug ... Bacto-Unidisk, 394 U.S. 784, 798 (1969) (providing overriding purpose of FDCA to serve public with "efficacy" and "safety"); United States v. Undetermined Quantities of Bottles ... Pets Smellfree, 22 F.3d 235, 238 (10th Cir. 1994) (demanding consistency between liberal construction of FDCA and overall goal of protecting public health); Premo Pharmaceutical Lab., Inc. v. United States, 629 F.2d 795, 802 (2d Cir. 1980) (describing FDCA's purpose); United States v. An Article of Food ... Nuglomin Lot 7056, 482 F.2d 581, 584 (8th Cir. 1973) (recognizing Act's overriding purpose of protecting public health). The Act purposely protects public health, and the FDA decides how to achieve that purpose. See United States v. Articles of Drug ... Promise Toothpaste for Sensitive Teeth, No. 83 C 6129, WL 5185, at *3 (N.D. Ill. April 25, 1986).

28. See Carchman, supra note 17, at 93 (1996) (noting FDA's limited ability to assert jurisdiction over cigarettes). In contrast, the FDCA does not exempt cigarettes from regulation, therefore, many
Since the passage of the FDCA in 1938, the FDA has held that cigarettes are beyond its jurisdiction unless manufacturers or vendors make affirmative health claims. According to the FDCA, only if a vendor claims or represents that a particular cigarette can cure, mitigate, treat, or prevent disease can the FDA regulate that cigarette as a drug. The FDA has the responsibility to protect the buying public from misleading information because in the circumstances of modern life, consumers are highly credulous and often beyond self-protection.

The FDCA defines drugs as either "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" or "articles (other than food) intended to affect the structure or any function of the body of man or other animals." The FDA defines a device as an instrument or other similar article "intended for use in the cure, mitigation, treatment or prevention of disease" or "intended to affect the structure or any function of the body." Thus, under the FDCA, the FDA has jurisdiction over nicotine-containing cigarettes if vendors intend that they treat a disease or affect the structure or function of the body.

In determining whether a product falls under the statutory definition of a drug or device, the FDA and courts often look to vendor intent. If a smoking critics advocate FDA regulation. Id. The FDCA provides grounds for FDA jurisdiction over drugs and delivery devices, but since its 1938 inception, the FDA has not exercised jurisdiction over tobacco. See Michael Whatley, Note, The FDA v. Joe Camel: An Analysis of the FDA's Attempt to Regulate Tobacco and Tobacco Products Under the Federal Food, Drug, and Cosmetic Act, 22 J. LEGIS. 121, 121 (1996) (noting FDA's previous position regarding tobacco regulation).

29. See Action on Smoking & Health v. Harris, 655 F.2d 236, 241 (D.C. Cir. 1980) (concluding cigarettes subject to FDCA if manufacturers make medical claims for their product).

30. See United States v. 46 Cartons ... Fairfax Cigarettes, 113 F. Supp. 336, 337 (D.N.J. 1953) (stating manufacturer representations can determine product's use). In 46 Cartons, the claimant marketed 46 cartons of cigarettes along with 51 leaflets entitled, "How Fairfax Cigarettes may help you." Id. at 336. The accompanying leaflet suggested that the product could effectively prevent many illnesses such as common cold, influenza, tuberculosis, and acute tonsillitis. Id. at 337.

31. See id. at 337 (discussing FDCA's function in light of manufacturer advertising and labeling). Due to the competitive nature of the tobacco industry, manufacturers often focus on advertising and labeling rather than altering prices or changing the product's quality. See id. Congress realized that manufacturers "tread[ed] near the statutory boundary," and noted that public consumers must be adequately informed regarding product purchases. See id. Therefore, the purposes of the FDCA is to protect vulnerable consumers who may be ignorant, unthinking, or credulous. See United States v. Article ... Sudden Change, 409 F.2d 734, 740. Moreover, courts should not provide a loophole through which those who take advantage of the weak and gullible can potentially escape the consequences of their actions. See id. (noting purpose of the FDCA); United States v. 250 Jars ... "Cal's Tupelo Blossom U.S. Fancy Pure Honey," 344 F.2d 288, 289 (recognizing court's need to protect public welfare).


34. See infra notes 35-48 and accompanying text (discussing vendor intent).

35. See National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 333 (2d Cir. 1977) (explaining relation between vendor intent and definition of drug); Action on Smoking & Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980)(acknowledging key role of vendor intent for determining whether product fits drug definition); Peter Bynum, A Stare Decisis Barrier to Regulating Cigarettes as Drugs,
vendor makes particular health claims about a product, such representations constitute direct evidence of vendor intent to "affect the body". If a vendor does not make claims regarding its product, the FDA must consider other factors to determine vendor intent. As such, the FDA often infers vendor intent through labeling, promotional material, advertising, and any other relevant source.

In determining whether to classify a product as a drug, the FDA may

---

12 J.L. & Pol. 365, 367 (1996) (discussing vendor intent and defining products as drugs). To determine vendor intent, courts often look to advertisements, labels, and promotional material. See U.S. v. Article . . . Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969) (noting advertisements, promotional material, and product labels determine vendor intent). Regardless of the actual physical effect of the product, the product is a drug if its labeling and promotional claims show intended uses that bring it within the definition of a drug. Id. Thus, a product is subject to regulation as a drug if vendors make certain promotional claims about the product. Id.

36. See Action on Smoking & Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980) (discussing potential impact of health claims). The earliest reported case attempting to define cigarettes as drugs was Federal Trade Commission v. Liggett & Myers Tobacco Company, 108 F. Supp 573 (S.D.N.Y. 1952), which discussed false advertising and the drug status of cigarettes. The Federal Trade Commission (FTC) alleged that a certain brand of cigarettes advertised as less irritating was a drug. Id. at 573. The advertising in question pertained to the manufacturer's representation that smokers could use the cigarettes without inducing any adversely effecting the nose or throat. Id.

In Liggett, the court used the FTC Act, not the FDCA, to determine whether the cigarettes were a drug. See Carchman, supra note 17, at 94 (noting FTC and FDCA's identical drug definitions). Any substance which has the potential to stimulate the senses can qualify, in some insignificant degree, as affecting bodily functions. See FTC Act § 15 (c), Pub. L. No. 63-203, 38 Stat. 717 (1914) (codified at 15 U.S.C. § 55(c) (1994)) (providing broad statutory definition of drug); see also Liggett, 108 F. Supp at 576 (setting forth consequences of overbroad FTC drug definition). Consequently, any article used in a manner anticipated by the manufacturer which comes into contact with any of the senses may constitute an article intended to affect the functions of the human body. See Liggett, 108 F. Supp at 576. As the court concluded, the legislators did not intend an all-inclusive literal interpretation of the clause. See id.

37. See infra notes 38-48 and accompanying text (discussing relevant factors to determine vendor intent).

38. See Action on Smoking & Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980) (recognizing well established principle whereby courts use all relevant sources to find manufacturer intent); National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334 (2d Cir. 1977) (outlining sources in which to derive or infer vendor intent); United States v. Article . . . Sudden Change., 409 F.2d 734, 739 (2d Cir. 1969) (acknowledging well-settled rule permitting courts to determine intended use of product through promotional claims); United States v. Kasz Enterprises, Inc., 855 F. Supp. 534, 539 (D.R.I. 1994) (deriving vendor intent through labeling, promotional material, advertising, or any other relevant source); Hanson v. U.S., 417 F. Supp. 30, 35 (D. Minn. 1976) (offering well-established rule of finding intended use of product through various sources); United States v 250 Jars, F. Supp. 208, 211 (E.D. Mich. 1963), aff'd, 344 F.2d 288 (6th Cir. 1965) (employing method of determining product's intended use through all relevant sources). Beyond examining a product's labels, courts look to various other information sources for guidance. See 250 Jars, F. Supp. 208 at 211 (stressing courts should examine all relevant sources); see also, United States v. Articles of Drug, 362 F.2d 923, 926 (3d Cir. 1966) (finding intended use through broadcasting channels); United States v. Millpax, Inc., 313 F.2d 152, 154 (7th Cir. 1963) (revealing intended use through disclaimer letter and magazine testimonials); Nature Food Centers, Inc. v. United States, 310 F.2d 67, 69 (1st Cir. 1962) (permitting claims made in lectures and class notes to show intent); United States v. Hohensee, 243 F.2d 367, 370 (3rd. Cir. 1957) (proving intent through promotional claims in graphic material and in oral representations).
look beyond the manufacturer's subjective intent and find actual therapeutic intent on the basis of objective evidence. Moreover, courts have determined that an analysis based solely on subjective intent could seriously diminish the effectiveness of regulatory agencies because it would allow a manufacturer to introduce dangerous articles into commerce on the unreasonable but good faith belief that the articles were indeed safe. Although the subjective intent of the manufacturer, seller, or distributor is often controlling, regulatory agencies may use the objective standard.

Through implementation of the objective intent standard, a standard which focuses on the reasonable expectations of the consumer, courts balance a manufacturer's interest in avoiding liability for unintended uses of the product with the need of protecting the public. In determining objective intent using the reasonable expectations test, courts must look beyond a product's label and the manufacturer's representations. Courts have considered other relevant evidence to include general public knowledge of the usefulness of similar products, advertising materials, the effectiveness of the product, and all other pertinent circumstances.

39. See National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334 (2d Cir. 1977) (expanding definition of drug to include objective evidence); National Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 789 (5th Cir. 1974) (stating factfinder should freely "pierce" manufacturer's subjective intent to find objective intent). In National Foods, the court acknowledged that vendor intent is the crucial element in the definition of a drug. See id. In addition to actual vendor intent, the factfinder should examine the objective intent behind the product. See id.; United States v. Kasz Enterprises, 855 F. Supp. 534, 539 (D.R.I. 1994) (finding vendor intent based on objective intent in promoting, distributing, and selling product). If consumers use a product for a purpose in which the vendor did not advertise or label, and the vendor is aware of this use, courts may find objective intent. See Kasz Enterprises, Inc., 855 F. Supp. 539-40 (D.R.I. 1994) (finding intended use through testimonials regarding product's ability to affect structure or function of body).


42. See N. Jonas & Co. v. EPA, 666 F.2d 829, 833 (3d Cir. 1981) (stating balancing test produced by implementation of objective standard).

43. See id. (noting broader scope of objective intent interpretation).

44. See id. (outlining additional relevant criteria); Mathews, 557 F.2d at 334 (noting sources for deriving intended use of product); United States v. Article . . . Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969) (listing relevant elements for determining objective intent); Hanson, 417 F. Supp. at 35 (identifying factors for determining intended use of product); see also United States v. 250 Jars, etc., of U.S. Fancy Pure Honey, 218 F. Supp. 208, 211 (E.D. Mich. 1963) (including descriptive leaflet as
In addition, courts determine objective intent largely based on foreseeability. Accordingly, a court may find intent to "affect the structure or function of the body" if it foresees that a large proportion of consumers would use the product to achieve such effects. Under this theory, the FDA asserts that a broad reading of intent is proper. Furthermore, courts have traditionally given broad interpretations to public welfare statutes, in particular, the FDCA.

The FDA and the courts traditionally interpret the FDCA as providing jurisdiction over cigarettes if manufacturers' advertising stated or implied therapeutic claims. Since its assertion of jurisdiction over cigarettes in July of 1995, the FDA interprets manufacturer intent based on indirect evidence. This unprecedented conclusion, which established that nicotine in cigarettes is a drug, places tobacco under the jurisdiction of the FDCA.

relevant source for determining intended use), aff'd, 344 F.2d 288 (6th Cir. 1965).

45. See United States v. Focht, 882 F.2d 55, 59-60 (3d Cir. 1989) (using foreseeability to establish vendor intent). But see Boeckman, supra note 25, at 1027 (noting that FDA regulations describing objective intent fail to mention foreseeable use). In using the foreseeable standard, the FDA severely departs from FDCA precedent. Id. In addition, the FDA looked to cases interpreting the FHSA and the Federal Insecticide, Fungicide, and Rodenticide Act (Insecticide Act). See generally United States v. Focht, 882 F.2d 55 (3d Cir. 1989) (construing FHSA); Jonas, 666 F.2d at 829 (construing Federal Insecticide Act); United States v. Articles of Banned Hazardous Substances Consisting of ... Baby Rattles, 614 F. Supp. 226 (E.D.N.Y. 1985) (construing FHSA); see also Boeckman, supra note 25, at 1027 (suggesting that courts examining vendor intent under FHSA and Insecticide Act lacked legislative history and precedent). The standard of objective intent under the FDCA has a deep legislative history; therefore, the FDA's resort to cases interpreting other federal statutes is improper. Id. at 1028.

46. See Proposed Regulations, supra note 4, at 41,479 (discussing foreseeability and its relation to vendor intent). The foreseeability approach prescribed by the FDA moves a tort standard into the language of the FDCA, but the court has yet to determine whether the FDCA permits such a reading. See Gregory S. Chernack, Developments in Policy: The FDA's Tobacco Regulations, 15 YALE L. & POL'Y REV. 399, 412 (1996) (examining implications of using foreseeability to determine objective intent).

47. See infra note 48 and accompanying text (providing rationale for broad interpretation of intent).

48. See Chernack, supra note 46, at 412 (noting courts provide strong and broad interpretations of public welfare statutes). In United States v. Park, the Supreme Court imposed strict liability in a criminal prosecution under the FDCA. United States v. Park, 421 U.S. 658, 670-72 (1975) (outlining Supreme Court treatment of statute involving public safety). In effect, courts may waive the requisite mens rea for criminal liability when a criminal statute serves the public welfare. See Chernack supra 46, at 412 (suggesting manufacturer need not know of dangers to be liable). Permitting strict liability in criminal situations provides support for a tort-style intent standard for cigarettes. Id. at 413.

49. See supra notes 35-48 and accompanying text (discussing basis for FDA jurisdiction over cigarettes). Congress realizes that the FDA cannot assert jurisdiction over cigarettes unless manufacturers make specific health claims. See Action on Smoking and Health v. Harris, 655 F.2d 236, 241 (D.C. Cir. 1980) (noting traditional view of Congress).

50. See Carchman, supra note 17, at 114 (implying unsupported basis for FDA assertion of jurisdiction over cigarettes). As a result, the FDA departed from its long-standing interpretation of the FDCA when it asserted jurisdiction over cigarettes. Id.

51. See Carchman, supra note 17, at 111-12 (providing FDA's finding that relegates nicotine to drug status). Nicotine, often described as a psychoactive drug, significantly contributes to tobacco addiction. See generally Michael C. Fiore, Tobacco Dependence and the Nicotine Patch: Clinical
B. Nicotine Conclusions

In reaching its conclusion, the FDA relied on general public awareness of the addictive, psychoactive, and pharmacological effects of nicotine. Since 1980, many organizations, such as the World Health Organization, the American Medical Association, the American Psychiatric Association, the American Society of Addiction Medicine, the Royal Society of Canada, and the Medical Research Council in the United Kingdom, have recognized and reported on the addictive features of nicotine. In addition, a 1991 FDA survey indicated that the vast majority of the tobacco industry's scientists understood the addictive features of nicotine.

Scientists determine whether a substance creates addiction by evaluating the compulsive or regular use of the product, the inability to stop using the product despite a desire to quit, and the existence of withdrawal symptoms. The use of these factors has produced ample evidence to support the FDA's conclusion that cigarettes are addictive. For instance, 87 per-

Guidelines for Effective Use, 268 JAMA 2687 (1992) available in 1992 WL 11638339 (noting nicotine's significant relation to tobacco dependence). Withdrawal from nicotine often causes craving, anxiety, irritability, hunger, restlessness, decreased concentration, drowsiness, and sleep disturbance. Id. at 2688.

52. See Proposed Regulations, supra note 4, at 41,484 (recognizing numerous reports regarding nicotine addiction). Addictive substances, like nicotine, achieve their effects by producing psychoactive (mood-altering) and chemical reactions in the brain that generate compulsive use of the substance. Id. at 41,485. Industry executives have refuted the assertion that nicotine causes addiction and have suggested that nicotine merely improves flavor and contributes to the smoking pleasure. See Lars Noah, Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products, 48 ALA. L. REV. 1, 12-13 (1996) (providing industry response to arguments suggesting nicotine causes addiction). The FDA has countered these claims by offering evidence that suggests cigarette manufacturers deliberately manipulate nicotine levels. Id. at 13-14. If true, this evidence would provide the FDA with the "previously elusive evidence" of drug use. Id. at 15. In an upcoming case aimed at recovering costs for Medicaid patients, Minnesota Attorney General Hubert H. Humphrey III intends to reveal as many of the estimated 33 million documents that demonstrate past tobacco industry misconduct. See Richard A. Melcher, Fanning the Flames for a Tougher Deal, Bus. WEEK, September 8, 1997 at 33 (acknowledging abundance of secret industry documents).

53. See Proposed Regulations, supra note 4, at 41,484 (listing organizations recognizing addic和平ness of nicotine). In 1994, the FDA's Drug Abuse Advisory Committee characterized nicotine as a drug and concluded that it causes addiction. Id.

54. See id. (noting 83.3 percent of principal tobacco industry investigators strongly agreed while 15.3 percent somewhat agreed that smoking produces addiction).

55. See id. at 41,485 (noting widely accepted definition of substance addiction). In addition, psychoactive and chemical effects on the brain are common components of addiction. See Michael S. Burkhard, Cigarette Classification a Burning Issue: New Evidence Could Lead to Drug Classification for Cigarettes, 6 LOY. CONSUMER L. REP. 116, 119 (1994) (providing common elements of addiction). Within seven to ten seconds after inhaling, nicotine reaches the brain and produces effects similar to adrenaline and acetylcholine. See id. (revealing nicotine's effect on brain and nervous system). Consequently, the heart beats faster, blood pressure rises, and the smoker experiences increased mental alertness. Id.

56. See Proposed Regulations supra note 4, at 41,485-86 (showing widespread consumer addiction to nicotine under contemporary definition of addiction). In addition, habit, pleasure-seeking, and
sent of people who smoke cigarettes smoke them every day, and nearly two-thirds of all smokers need their first cigarette within one-half hour of awakening. In addition, although 70 percent of smokers report they would like to quit, only three percent achieve long-term success. Also, in their efforts to quit, smokers experience numerous withdrawal symptoms including irritability and hunger.

Numerous sources have disseminated this dismal information to the public, which now recognizes the addictive and pharmacological properties of nicotine. Because of the vast documentation and compelling scientific evidence, manufacturers must foresee the potential effects of cigarettes on the structure or function of the body. Although manufacturers claim their products are for taste and smoking pleasure only, the objective intent standard would hold that manufacturers foresee and intend the consequences of consumers’ use of their products.

Given this data, the FDA concluded that:

"(1) the nicotine in cigarettes and smokeless tobacco products is a drug, achieving its effect through chemical action within the body; (2) cigarettes and smokeless tobacco are drug delivery systems whose purpose is to deliver nicotine in a manner in which it can be most readily absorbed by the consumer, and are, therefore, devices; and (3) cigarettes and smokeless tobacco products are combination products that the agency has

self-medication significantly contribute to addiction. See Fiore, supra note 51, at 2688 (discussing other components of addiction).

57. See Proposed Regulations, supra note 4, at 41,486 (showing compulsive and regular use of cigarettes).

58. See id. (reviewing statistics which show smokers’ desire but inability to quit). Nicotine produces the “high” that smokers experience. See Henges, supra note 3, at 576 (noting feeling of euphoria supplied by nicotine). This presence of nicotine in the brain along with its effects contributes to the smoker’s inability to quit. Id.

59. See Henges, supra note 3, at 576 (stating some effects of nicotine withdrawal); supra note 51 and accompanying text (listing withdrawal symptoms). Smokers will continue to smoke to combat the adverse side effects of nicotine withdrawal. Henges, supra note 3, 575-76.

60. See Proposed Regulations, supra note 4, at 41,488 (noting existence of large body of evidence which discusses nicotine’s effects on mood). Even if studies indicate that nicotine is not a physically addictive substance, it nonetheless affects the structure or function of the body by producing increased alertness and relaxation. See Burkhard, supra note 55, at 120 (showing how nicotine affects body). If cigarettes and nicotine did not provide enjoyable sensations, the smoker would discontinue purchasing cigarettes. Id. Thus, by claiming that they do not intend nicotine to affect the function of the body, that is “for nicotine to create a pleasurable physical sensation,” the tobacco companies are basically stating that they do not care if their products sell. See id.

61. See Proposed Regulations, supra note 4, at 41,482 (stating public awareness provides manufacturers with knowledge of foreseeable use of their products). In 1988, the Surgeon General issued a report that discussed the addictiveness of cigarettes and concluded that nicotine is a drug that causes addiction and that the pharmacological and behavioral processes that cause tobacco addiction are similar to those that cause addiction to cocaine and heroin. Id. at 41,484.

62. See id. at 41,483 (asserting manufacturers foresee consequences of consumers’ tobacco use); see also supra note 46 and accompanying text (explaining foreseeability).
the discretion to regulate using drug authorities, device authorities, or a combination of both authorities.  \textsuperscript{63}

The FDA subsequently classified cigarettes and smokeless tobacco as drug-delivery devices because they are essentially drug delivery systems. \textsuperscript{64} A drug delivery system, as defined by the FDA, is any instrument, implement, machine, or device-like product whose primary purpose is delivery of a drug; and that the distribution of the drug is accomplished by a drug product. \textsuperscript{65} Cigarettes and smokeless tobacco fall within this definition because they contain a drug, nicotine, and deliver that drug to certain parts of the body. \textsuperscript{66} Accordingly, the FDA noted that cigarette classification under the device definition would be consistent with the traditional approach to device classification. \textsuperscript{67}

C. The Regulations

On August 28, 1996, the FDA issued their controversial regulations in attempt to reduce tobacco consumption among young people. \textsuperscript{68} The regulations prohibit, among other things: the sale of cigarettes to persons under the age of eighteen years and require retailers to verify the age of the purchaser; prohibit sale through vending machines or self-service displays, unless the sales occur in adult-only locations; prohibit the distribution of free samples or so called kiddy packs, which contain fewer than twenty cigarettes; restrict advertisements to black-and-white-print and text-only format, unless the advertisement is in an adult-only facility with vending machines or self-service displays and is not visible from the outside or the advertisement appears in an adult publication; prohibit outdoor advertisements, such as billboards, posters, and placards, that are within 1000 feet of schools and playgrounds; prohibit the sale of non-tobacco products, such as T-shirts, hats, and posters; and restrict the sponsoring of sporting events and teams to just the corporate name. \textsuperscript{69} The FDA’s objective is to reduce the percentage of minors using tobacco products by fifty percent. \textsuperscript{70}

\begin{itemize}
  \item[63.] \textit{See id.} at 41,521-22 (defining cigarettes as drug delivery systems).
  \item[64.] \textit{See id.} at 41,521-23 (discussing rational for device classification of cigarettes).
  \item[65.] \textit{See id.} at 41,521 (defining device-like product).
  \item[66.] \textit{See} Proposed Regulations \textit{supra} note 4, at 41,522 (explaining cigarette and smokeless tobacco classification as drug delivery system). The FDA compared a cigarette to a metered-dose inhaler, "an instrument that converts a drug into an aerosolized form for inhalation and delivery to the lungs for absorption into the bloodstream." \textit{Id.}
  \item[67.] \textit{See id.} at 41,525 (recognizing consistency with traditional FDA classifications).
  \item[68.] \textit{See generally id.} (detailing FDA’s regulations).
  \item[69.] \textit{See id.} at 41,326-28 (outlining FDA’s regulations); \textit{see also} Gostin, \textit{supra} note 18, at 400 (providing specifics of proposed regulations).
  \item[70.] \textit{See Proposed Regulations, supra} note 4, at 41,314 (discussing “Healthy People 2000” objective to cut adolescent smoking in half).
\end{itemize}
If the FDA does not achieve this goal within seven years, the agency will consider additional restrictions. 71

As expected, the FDA's regulations faced stiff resistance from the tobacco industry and its supporters. 72 Since 1905, the tobacco industry has effectively avoided a variety of similar initiatives by implementing carefully planned strategies. 73 Despite the power of the industry and its past success in challenging regulatory efforts, eighty six percent of the general public and eighty four percent of the people in tobacco-producing states support FDA regulation. 74

III. JUSTIFICATIONS FOR REGULATION

Early efforts to control tobacco focused on the need to educate smokers about the health consequences of tobacco consumption. 75 In 1965, Congress enacted the FCLAA which reinforced the notion that smokers would voluntarily assume the risks associated with smoking. 76 Given new evi-

71. See id. (stating FDA will implement additional measures if regulations do not achieve objective).

72. See generally Coyne v. Beahm, Inc. v. United States Food & Drug Admin. 958 F. Supp. 1060 (M.D.N.C. 1997) (discussing industry challenge to FDA's assertion of jurisdiction to regulate tobacco); see infra note 73 and accompanying text (discussing industry challenges to previous regulatory efforts).

73. See Arno, supra note 6, at 1259 (noting historical success of tobacco industry when challenging potential regulations). In 1965, for example, the industry turned a new warning label law into their own defense, which for the past thirty years has protected manufacturers from liability. See Alix M. Freedman, Burning Questions: Tobacco Pact's Limits, WALL ST. J., June 23, 1997, at A1 (mentioning examples where industry manipulates regulations to their advantage); Myron Levin, Tobacco Foes Scour Pact for Smoke and Mirrors Settlement: Activists fear accord may yet give industry a way to sidestep significant FDA regulation of nicotine, LA TIMES, June 22, 1997, at A1 (showing manufacturer ability to outflank new regulations). In 1971, manufacturers voluntarily removed their advertisements from television and radio; however, this also proved advantageous to the industry because of the inability of upstart companies to obtain a significant market share. See Freedman supra at A1 (providing example how tobacco industry worked around regulation). The tobacco lobby contributes significantly to the industry's success. See Gostin, supra note 18, at 411 (providing reason why Congress typically excludes cigarettes from major food and drug regulation). Studies indicate that the most significant factor associated with opposition to tobacco control measures in the Congress was the amount of money received from the tobacco industry in the form of campaign contributions. See Arno, supra note 6, at 1261-62 (noting substantial majority of Congress receives money from tobacco industry). Indeed, the industry has implemented numerous strategies to combat tobacco regulation including the following: litigation challenging the FDA's jurisdiction, threats of litigation against the media; lobbying and political contributions to gain influence in Congress; advertising campaigns with anti-government themes; and the manipulation of the public comment component of the regulatory process. Id.

74. See Jim Roach, Patton is off Base on Tobacco, COURIER-J. (Louisville), Sep. 27, 1996, at 15A (revealing public support of FDA regulation). In addition, 78 percent of smokers support the FDA. Sean Cahill, Letters to the Editor: Big Tobacco Calls in its Chips, WALL ST. J., Jan. 13, 1997, at A19.

75. See Gostin, supra note 18, at 411 (providing early strategies for regulation). Consumers should have access to all information regarding tobacco so they can indeed make informed choices about tobacco use. See id. (suggesting consumers buy without full knowledge of product).

76. See supra note 17 and accompanying text (discussing history of FCLAA).
dence that smoking may not be a voluntary health risk, arguments for stricter regulation have risen sharply. In addition, the following three issues provide a compelling argument for the regulation of tobacco: the health risk to smokers and nonsmokers; the increase in youth smoking; and manufacturer knowledge and intent. Our evolving understanding of cigarettes will profoundly affect the environment in which the industry will challenge the FDA.

A. Risk to the Public Health

Many individuals do not voluntarily subject themselves to the harmful attributes of tobacco products; therefore, the law should provide the necessary protections. The need for protection arises where a nonsmoker involuntarily breathes tobacco smoke emitted by a smoker. This smoke, commonly referred to as secondhand smoke or environmental tobacco smoke ("ETS"), contains many of the same carcinogenic and toxic agents as the mainstream smoke inhaled by smokers.

ETS poses major concerns for nonsmokers. In December of 1992, the Environmental Protection Agency ("EPA") concluded that ETS is a carcinogen that causes a plethora of diseases in nonsmokers, such as lung cancer and pneumonia, and is also responsible for over 3000 deaths per year.

77. See infra notes 127-30 and accompanying text (discussing addiction and its elimination of voluntary choices).

78. See Gostin, supra note 18, at 411 (raising justifications for tobacco regulation); supra note 6 and accompanying text (mentioning three justifications for regulation); infra notes 80-134 and accompanying text (discussing justifications of tobacco regulation).

79. See Gostin, supra note 18, at 411 (noting change in tobacco understanding alters environment for contesting regulations). See supra note 73 and accompanying text (discussing prior industry strategies against regulatory efforts).

80. See Arno, supra note 6, at 1258 (noting compelling need to protect individuals from situations in which they have no control).


82. See id. (recognizing growing concern of nonsmokers that ETS exposes nonsmokers to various risks). ETS contains a combination of smoke given off by the burning end of a cigarette, pipe, or cigar, and the smoke exhaled from the lungs of smokers. See U.S. ENVIRONMENTAL PROTECTION AGENCY, SECONDHAND SMOKE: WHAT CAN YOU DO ABOUT SECONDHAND SMOKE AS PARENTS, DECISIONMAKERS, AND BUILDING OCCUPANTS, (1993). ETS contains over 4000 substances, more than 40 of which are known to be carcinogenic. Id.

83. EPA Report, supra note 81, at 1-1.

84. Id. The EPA classified ETS as a Group A carcinogen because evidence demonstrated a causal link between ETS and lung cancer. Id. at 1-2, 1-3. The federal government has regulated common Group A carcinogens, such as asbestos and benzene, but they have yet to provide similar regulations for ETS. Susan Ross, Second-Hand Smoke: The Asbestos and Benzene of the Nineties, 25 ARIZ. ST. L.J. 713, 724 (1994). Although exposure to asbestos and benzene may yield similar results to exposure to ETS, the federal government fails to regulate ETS. See id. at 717 nn.43-50, 721 nn.99-101 (explaining health risks associated with exposure to benzene and asbestos).
Because millions of people smoke, "ETS is a ubiquitous air pollutant" which exposes every American to a substantial health risk.\(^{85}\) As the Superior Court of New Jersey stated:

The evidence is clear and overwhelming. Cigarette smoke contaminates and pollutes the air, creating a health hazard not merely to the smoker, but to all those around her who must rely upon the same air supply. The right of an individual to risk his or her own health does not include the right to jeopardize the health of those who must remain around him . . . .\(^{86}\)

When hazards threaten the public health, the government has the undisputed prerogative to maintain the public's safety pursuant to its police powers.\(^{87}\) For over a century, courts have struggled to articulate a precise definition of police power.\(^{88}\) Nevertheless, courts generally conclude that

\[^{85}\text{See Ross, supra note 84, at 713-15 (presenting dangers of secondhand smoke). The smoke emitted from a cigarette contains at least thirty different pollutants, each presenting a potential health hazard. See Osborne M. Reynolds, Jr., Extinguishing Brushfires: Legal Limits on the Smoking of Tobacco, 53 U. Cin. L. Rev. 435, 437 (1984). From the average cigarette, sidestream smoke and mainstream release approximately seventy milligrams of dry particulate matter and twenty-three milligrams of carbon monoxide. Id. The dry matter can result in eye and nasal irritation as well as coughing, wheezing, and sore throats. Id. Inhaling carbon monoxide creates additional concerns because it combines with hemoglobin in the blood to form carboxyhemoglobin, which reduces the ability of the circulatory system to deliver oxygen to the organs of the body. Id. at n.12. In addition to the exposure to obvious health dangers, many nonsmokers argue that tobacco smoke interferes with their enjoyment of life due to the unpleasant atmosphere it creates, particularly the odor. See id. at 438 (revealing additional interferences with rights of nonsmokers).}\]


\[^{87}\text{See U.S. CONST. amend. X, § 10. The Tenth Amendment provides that "the powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." Id. Accordingly, the several States have the police powers to protect the health and safety of its citizens. See Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2245 (1996) (noting States' traditional exercise of police powers to protect health and safety of public); Jacobson v. Massachusetts, 197 U.S. 11, 25 (1904) (stating that police powers permits states to enact certain regulations); Steven V. Kenney, Criminalizing HIV Transmission: Lessons from History and a Model for the Future, 8 J. CONTEMP. HEALTH L. & POL'Y 245, 253 (1992) (discussing constitutional basis for public health laws).}\]

\[^{88}\text{See Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905) (showing refusal of Court to define limits of police power); Stone v. Mississippi, 101 U.S. 814, 818 (1879) (recognizing Supreme Court's unsuccessful attempts to define police power). While noting the difficulty in applying an abstract definition of police power, the Court stated that it was always easier to determine whether a particular case comes within the scope of the power. See Stone, 101 U.S. at 818. Black's Law Dictionary defines police power as:}\]

[a]n authority conferred by the American constitutional system in the Tenth Amendment, U.S. Constitution, upon the individual states, and, in turn, delegated to local governments, through which they are enabled to establish a special department of police; adopt such laws and regulations as tend to prevent the commission of fraud and crime, and secure generally the comfort, safety, morals, health, and prosperity of its citizens by preserving the public order, preventing a conflict of rights in the common intercourse of the citizens, and insuring to each an uninterrupted enjoyment of all the privileges conferred upon him or her by the general laws.
the police power extends to all matters affecting the public health or morals.89

The arena of public health and safety is primarily a matter of local concern; therefore, courts traditionally afford the states greater latitude in exercising their police powers.90 The broad array of police powers authorizes the government to legislate in order to protect the lives, limbs, health, comfort, and quiet of all persons.91 The State has ample discretion in implementing authoritative bodies of law, so long as the rules and regulations do not contravene the Constitution.92

Currently, state and local governments have enacted the majority of regulations dealing with the tobacco problem pursuant to their police power.93 Courts have not hesitated to uphold such regulations and restrictions.94 When a non-profit group, Operation Badlaw, Inc. (hereinafter "Badlaw"), claimed that certain regulations limiting smoking in public places violated its right to equal protection, the United States District Court for the Southern District of Ohio concluded that the regulations were constitutional and a legitimate exercise of the state's police power.95

In rejecting Badlaw's equal protection claim, the court noted that smoking does not rise to the level of a fundamental right, nor was the organization a member of a suspect class.96 Thus, the burden fell on Badlaw to prove that the regulations did not have a rational basis.97 Badlaw argued that the existence of an exemption provision made the regulations irra-

89. See Noble State Bank v. Haskell, 219 U.S. 104, 111 (1911) (offering broad application of police power); Stone, 101 U.S. at 818 (1879) (explaining scope of police powers).
90. See Medtronic, 116 S. Ct. at 2245 (allowing States to legislate matters of local concern). Public health and safety are primarily matters of the States. See id. at 2246 (noting primacy of States in matters of health despite increasing involvement at federal level).
91. See id. at 2245 (recognizing expansive power of States to legislate matters of health and safety); Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 756 (1985) (discussing traditional interpretations of police power).
93. See Reynolds, supra note 85, at 449 (attributing current regulation of smoking to States' police power). State and local governments are politically closest to the people, therefore they are most responsive to public demands. Id. at 439.
94. See id. at 449 (noting success of local regulations concerning tobacco problem).
95. See Operation Badlaw, Inc. v. Licking County Gen. Health Dist. Bd. of Health, 866 F. Supp 1059 (S.D. Ohio 1992) (upholding constitutionality of smoking limitations). The defendants passed the regulations based on the premise that "secondhand smoke is acutely harmful to nonsmokers with cardiovascular or respiratory diseases, that smoking in enclosed areas is a public nuisance, and that nonsmokers are currently unable to protect themselves against these hazards." Id. at 1063. The plaintiff's attacked the constitutionality of the rules and questioned whether the passage of the regulations constituted a legitimate exercise of the county's police power. Id.
96. See id. at 1064 (applying rational basis test to determine constitutionality of regulation).
97. See id. (stating rational basis analysis requires plaintiff to convince court of irrationality). The court does not need to know the actual reason for enacting the statute and may even hypothesize as to any possible legitimate state objectives. Id.
tional because the exemption would protect nonsmokers in only select environments, although the threat of harm to the nonsmoker remained the same in all areas. 98 The county responded by stating that the purpose of the regulations was to provide protection to nonsmokers in traditionally public areas and to minimize the effect on smokers in private places. 99 The court noted that the regulations may treat individuals differently; however, the regulations were not unconstitutional because they did not impinge upon a fundamental right and had a rationally related and permissible state objective. 100

B. Risk to Children

Although certain regulatory actions would fail as unjustified regarding the adult population, the government, under its parens patrie powers, may take action in order to protect the nation's children. 101 Such action becomes especially necessary in the advertising context because of the vulnerability of children. 102 Because of children's inability to accurately interpret messages, advertisements directed toward a younger audience cannot fulfill the legitimate purpose of providing meaningful information about products in the marketplace. 103 Thus, society's interest in protect-

98. See id. (outlining basis of plaintiffs' argument). Smoking in enclosed public places, such as healthcare facilities and governmentally-owned structures, was absolutely prohibited; however, certain other public places, such as restaurants and hotels could apply for exemptions and could designate areas for smoking. Id. at 1063. Bars, bowling alleys, and pool halls were entirely exempt from the regulation, so long as they displayed a sign stating that a non-smoking area was not available. Id.

99. See id. at 1064 (providing defendant's argument). This would ensure that nonsmokers who did not wish to come into contact with secondhand smoke knew in advance that smoke may be present. Id.

100. See Badlaw, 866 F. Supp at 1064-65 (finding rational basis for enactment of regulations). Although such regulations may limit the nonsmoker's exposure to ETS, they often prove inadequate because of the nature of secondhand smoke. See Ross, supra note 84, at 726-27 (explaining potential inadequacies of secondhand smoke regulation). Specifically, ETS has two phases: the particulate phase, where the smoke particulate matter is visible, and the vapor phase, where the smoke is a gas. See EPA Report, supra note 81, at 2-2 (describing ETS). Although the separation of smokers from nonsmokers may limit a nonsmoker's exposure to the particulate phase, nonsmokers still are exposed to the vapor phase of ETS, because in its vapor phase, ETS readily disperses throughout common airspace. See Ross, supra note 84, at 726 (discussing potential ineffectiveness of regulations attempting to limit exposure of secondhand smoke). Consequently, to protect nonsmokers in common areas such as at work, at home, and in public places, more restrictive controls are necessary. Id.


102. See supra note 9 and accompanying text (discussing inability of minors to maturely interpret advertising).

103. See Prince v. Massachusetts, 321 U.S. 158, 168 (1944) (finding state's authority over children's activities broader than authority over similar actions of adults); Gerald Thain, Suffer the Hucksters to Come unto the Little Children? Possible Restrictions of Television Advertising to Children Under Section 5 of the Federal Trade Commission Act, 56 B.U. L. REV. 651, 683-84 (1976)
ing and nurturing children outweighs any pecuniary loss which advertising manufacturers may suffer as a result of prohibiting such advertisements. 104

Because the cigarette industry loses approximately 1.7 million smokers each year (1.3 million quit, 400,000 die), tobacco manufacturers must recruit new smokers to realize a profit. 105 To replace the number of lost smokers, the industry focuses its advertisements and promotional material on the precarious minor population which constitutes approximately ninety percent of all new smokers. 106 The themes of these advertisements, such as youthful vigor, sexual attraction, and independence, achieve particular success because they deal with those issues which often preoccupy adolescents. 107 The tobacco industry’s behavior creates major concerns given the health dangers of smoking and the fact that every state prohibits the sale of cigarettes to persons under the age of eighteen. 108

(indicating advertisements’ inability to achieve purpose when directed toward minors).

104. See Thain, supra note 103, at 684 (stating protection of minors outweighs potential losses to advertisers). When manufacturers sold penny candy to children in “break and take packages,” the Supreme Court held that the merchandising induced children to purchase inferior quality candy and took advantage of their inability to understand the gambling involved. See Federal Trade Comm’n v. R.F. Keppel & Bro., Inc., 291 U.S. 304, 306-07 (1933) (finding validity of order forbidding certain trade practices because of children’s inability to protect themselves). Although no fraud or deception had occured, the practice induced children, “too young to be capable of exercising an intelligent judgment of the transaction,” to purchase a less desirable product of inferior quality. Id. at 309; see also Federal Communications Comm’n v. Pacifica Found., 438 U.S. 726, 749 (1978) (noting well-being of youths justifies regulation of otherwise protected expression); Ginsberg v. New York, 390 U.S. 629, 640-41 (1968) (recognizing State interest in safeguarding children from abuses which might prevent growth and development); Prince, 321 U.S. at 165 (emphasizing protection of children in order to foster growth into independent well-developed citizens).


106. See Joseph R. DiFranza, RJR Nabisco's Cartoon Camel Promotes Camel Cigarettes to Children, 266 JAMA 3149, 3149 (1991) (stressing obvious need of industry to replace lost smokers with children and adolescents). One study demonstrated the pervasiveness of tobacco brand names, logos, and advertising messages when it found that 30 percent of three year old children and 91 percent of six year old children associate the “Joe Camel” cartoon character with cigarettes. See generally Paul M. Fischer, Brand Logo Recognition by Children Aged Three to Six Years: Mickey Mouse and Old Joe the Camel, 266 JAMA 3145 (1991) available in 1991 WL 4874578 (noting ubiquitous images and messages conveyed to young people).

107. See Law, supra note 20, at 914 (providing rationale behind themes of cigarette advertisements). Advertisements effectively influence a young audience because the majority of smokers begin smoking before age 20, and approximately one half begin before age 14. Id. In fact, in just three years of advertising, Camel’s “Old Joe” cartoon increased the percentage of underage Camel smokers from 0.5% to 32.8%. See DiFranza, supra note 106, at 3151 (demonstrating influence of advertising on children). Since the implementation of the cartoon camel, Camel’s sales to minors have increased from approximately $6 million to $476 million per year. See id. (noting increase in sales to minors represents approximately 25% of Camel’s total sales).

108. See Proposed Regulations, supra note 4, at 41,315 (noting illegality of tobacco sales to minors); see also Harder, supra note 105, at 405 (providing unacceptable statistics and circumstances sur-
Many state and local governments have enacted measures in an attempt to limit assaultive advertising which negatively influences the credulous public. For example, in *Penn Advertising v. Mayor and City Council of Baltimore,* the United States District Court for the District of Maryland upheld an ordinance prohibiting cigarette advertising on billboards located in certain designated zones within Baltimore City. The court determined that the ordinance furthered a substantial state interest by preventing minors from purchasing and consuming cigarettes. In addition, the ordinance directly advanced state interest and was narrowly tailored to serve its purposes.

---


111. See generally Penn Adver. v. Mayor & City Council of Baltimore, 862 F. Supp. 1402 (D. Md. 1994) (finding substantial government interest in ordinance that promoted compliance with state laws). In reaching its conclusion, the court relied on the four prong test for determining the constitutionality of restrictions on commercial speech. See *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n,* 447 U.S. 557, 566 (1980) (establishing four prong test to determine commercial speech issues). In applying *Central Hudson,* courts must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it must at least concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest. See *Central Hudson v. Public Serv. Comm’n,* 447 U.S. 557, 566 (1980).

In addition to First Amendment issues, the court considered whether federal law preempted the ordinance. See *Penn Adver.,* 862 F. Supp. at 1414-20 (discussing issue of preemption). To determine the extent of federal preemption of state regulation of cigarette advertising, courts look to the FCLAA as interpreted by the Supreme Court in *Cipollone v. Liggett Group, Inc.* See 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-41 (1994)); Cipollone v. Liggett, 505 U.S. 504 (1992); see generally Edward O. Correia, *State and Local Regulation of Cigarette Advertising,* 23 J. LEGIS. 1 (1997) (examining scope of FCLAA preemption according to Supreme Court guidelines). Using the *Cipollone* standard, courts must determine “whether the legal duty that is a predicate to the common law action constitutes ‘a requirement or prohibition based on smoking and health . . . imposed under State law with respect to advertising or promotion . . . ’” *Cipollone,* 405 U.S. at 524.

112. See *Penn Adver.,* 862 F. Supp. at 1406 (finding substantial government interest in decreasing cigarette purchases of minors). Article 27, § 404 of the Maryland Code provides that “it is unlawful for any person engaged in the manufacture or sale of cigarettes to sell, barter or give cigarettes to an individual under the age of 18.” MD. CODE ANN., 27 § 404 (1992). This section prohibits the sale of cigarettes to minors, however, it does not expressly prohibit a minor from purchasing cigarettes. See *Penn Adver.,* 862 F. Supp. at 1406 (noting only sellers can violate section 404). The court, nevertheless, held that the ordinance would reduce the exposure of minors to stimuli encouraging the purchase, thereby decreasing the number of illegal transactions under sec. 404. See id. (finding ordinance advances public policy and provides substantial government interest).

113. See *Penn Adver.* 862 F. Supp. at 1414 (concluding ordinance directly advances City's substantial interest). The court adhered to the judicially-recognized proposition that advertising increases consumption. See id. (recognizing advertising leads to consumption). The court noted that because of the impressionable nature of minors, billboard advertising would have a greater impact on the youthful population than on the adult. See id. (noting susceptibility of youngsters to advertising). By restricting
Similarly, in *General Food Vending Inc. v. Town of Westfield*, the court upheld the constitutionality of an ordinance banning cigarette vending machines. In their challenge to the ordinance, the vendors argued that the town’s decision of a total ban was not rationally related to its goal of preventing the sale of cigarettes to minors. Specifically, the companies asserted that locking devices on the machines would be equally effective as a total ban and that the equal protection clause required the town to choose a less restrictive means. In rejecting this theory, the court relied on the holding in *C.I.C. Corp. v. East Brunswick Tp.* which held that the prohibition of vending machines does not involve a suspect class or fundamental right and that the prohibition need only be rationally related to a legitimate governmental interest to satisfy equal protection and substantive due process concerns.

In applying this logic, the *Westfield* court concluded that the total ban unequivocally passed the rational basis test. The court noted: "[A]ll that the rational basis test requires is that the alternative chosen bear some logical relationship to the end sought." The choice to totally ban the vending machines was not irrational because of the existence of a less harsh alternative of locking devices. The availability of cigarettes to minors provided a legitimate governmental concern, and the total ban of advertising, the ordinance will reduce the demand among minors, which in turn will decrease the number of § 404 violations. See id. (stating decrease in minor consumption directly advances substantial government interest). In addition, the court determined that the purpose of the ordinance was to further effectuate s. 404 and was not based on smoking and health. See Penn Advert., 862 F. Supp. at 1417 (noting purpose of ordinance). Therefore, the FCLAA did not preempt the ordinance. See id.


See *id.* at 446, 672 A.2d at 762 (setting forth vending machine company’s violation of equal protection arguments). In addition, the vendors contended that the ordinance constituted a taking and violated the contract clause because the ordinance essentially destroyed the value of their business in Westfield. *Id.*

See *id.* (providing essence of plaintiffs’ argument). The locking mechanism of the vending machines requires human activation. *Id.* at 445, 672 A.2d at 762. The plaintiffs urge that human intervention will just as effectively eliminate youth access to the machines as will a total ban. See *id.* at 449, 672 A.2d at 763 (showing plaintiffs’ misunderstanding of precedent).

See *General Food Vending, Inc.*, 288 N.J. Super. at 448-49, 762 A.2d at 763 (relying on previous case that set forth legitimacy of prohibition on vending machines); *C.I.C. Corp. v. Township of East Brunswick*, 266 N.J. Super. 1, 14, 628 A.2d 753, 760 (1993).

See *General Food Vending Inc.*, 288 N.J. Super. at 450, 762 A.2d at 764 (stating rational basis test requires legitimate governmental objective).

See *id.* at 449-50, 762 A.2d at 764 (finding rational basis for total ban despite existence of alternative). The court further explained that "[O]nce a governmental objective is determined to be legitimate, the relative effectiveness of the alternative means considered to accomplish the goal is irrelevant." *Id.*
vending machines served that objective. 123

C. Risk Assumed By Consenting Adults

Although adults may voluntarily engage in hazardous activities, the government has a moral obligation to regulate such risks. 124 Given the conclusive data linking dangers and diseases to tobacco products, the justification to regulate tobacco is as strong as the justification to regulate other voluntarily assumed risks. 125 Although smoking-related hazards provide a strong incentive for comprehensive regulation, this possibility nevertheless provokes controversy because “adults are thought to be capable of weighing any perceived benefits and risks of engaging in a dangerous activity.” 126

Indeed, the primary issue concerning regulation of voluntarily assumed risks often depends on whether consumers can in fact make voluntary choices about product use. 127 The tobacco industry and its advocates claim that consumers are aware of the addictive nature of nicotine and that this knowledge affords consumers a voluntary choice to start smoking. 128 Conversely, tobacco critics argue that addiction and dependency limit smoker autonomy. 129 The crux of this debate centers on whether the tobacco industry willfully manipulates the content of nicotine in cigarettes, thus intensifying physiological and psychological dependence. 130

123. See C.I.C. Corp., 266 N.J. Super. at 15-16, 628 A.2d at 761 (recognizing total ban serves legitimate objective). In C.I.C Corp., the court noted that in making legal distinctions, there is often a need for a fixed point or line. See id. at 15, 628 A.2d at 761 (noting need for points to determine where change takes place). When no precise mathematical or logical way for drawing this line exists, courts must accept the decision of the legislature unless the courts can determine that the line strays very wide of a reasonable mark. Id. The town decided that a fixed point or line was necessary in preventing minors’ access to cigarettes through the use of vending machines. Id. Applying this logic, the court concluded that anything short of a total ban would not achieve the desired results. Id.

124. See Arno, supra note 6, at 1258 (discussing government obligation to protect adults from voluntarily assumed risks).

125. See id. (justifying regulation of voluntarily assumed risks).

126. See id. (noting controversy surrounding regulation of voluntary activities). But see supra note 18 and accompanying text (suggesting consumer inability to protect themselves from risks).

127. See Arno, supra note 6, at (questioning whether smokers can make reasoned and uncoerced decisions about smoking).

128. See id. (offering industry views surrounding voluntary choice issues).

129. See id. (suggesting addiction impairs smokers’ freedom to choose whether to smoke).

130. See id. (emphasizing critical debate surrounding nicotine manipulation and lack of voluntary choice). According to a former Philip Morris scientist who worked seven years in the industry as Director of Applied Research, cigarette manufacturers deliberately manipulated the level of nicotine in their products to overcome “the naturally-occurring variability of nicotine in tobacco plants.” Declaration of Former Philip Morris Employee William A. Farone, WALL ST. J., April 1, 1996, at 2, available in 1996 WL 259477 (acknowledging industry awareness that cigarettes without substantial nicotine would not sell). In addition, most industry scientists firmly believed that nicotine created an individual’s desire to smoke, and the smoker’s acceptance of the cigarette correlated to the amount of nicotine the product contained. See id. (supporting notion that manufacturers research and develop
To clarify this dilemma, anti-smoking activists have urged lawmakers to pass legislation forcing cigarette manufacturers to disclose the additives and ingredients in their products.\textsuperscript{131} In opposition, the tobacco industry has asserted that disclosure laws would force them to reveal valuable trade secrets.\textsuperscript{132} Nevertheless, in February 1997, a federal judge ruled that a Massachusetts statute requiring complete disclosure of cigarette ingredients is lawful, thereby clearing the way for the state to implement the first law of its kind nationwide.\textsuperscript{133} In holding this law constitutional, the District Court of the United States for the District of Massachusetts declared that the state's right to protect public health supersedes congressional intent to protect the tobacco industry's commercial interest.\textsuperscript{134}

IV. THE PROPOSED TOBACCO SETTLEMENT

A. Problems with the Settlement

In April of 1997, tobacco foes achieved victory when a North Carolina federal court ruled that the FDA had a statutory right to regulate tobacco.\textsuperscript{135} In June, however, forty state attorneys general and the tobacco industry reached a landmark agreement which some experts fear will severely limit the effect of the FDA's declared right.\textsuperscript{136} Although the set-

methods to manipulate nicotine levels). To better understand the workings of nicotine, the industry conducted a significant amount of research to determine the drug's effect on various body parts and functions, such as brain waves, brain receptors, and the cardiovascular system. See id. at 3-4 (providing comprehensive list of industry tests used to understand relationship between nicotine and smoker's needs); see also supra note 60 and accompanying text (discussing correlation between level of nicotine in cigarettes to cigarette sales).


132. See Phillips, supra note 131, at A1 (providing industry's argument in opposition to disclosure laws).


134. See id. at 2 (stating implications of disclosure law).

135. See generally Coyne Beahm, Inc. v. United States Food & Drug Admin., 958 F. Supp. 1060 (M.D.N.C. 1997) (authorizing FDA to regulate tobacco). In Coyne, the court inquired whether Congress had displayed clear intent to withhold from FDA jurisdiction the power to regulate tobacco products as customarily marketed. Id. at 1066. Finding that the legislative history of the FDCA did not indicate Congressional intention to exempt tobacco from the Act, the court asserted that the FDCA applies to any product that meets one of the broad definitions of the Act, and the absence of specific discussion on a highly visible product did not prohibit regulation of that product under the Act. See id. at 1067 (summarizing court's conclusion).

136. See Levin, supra note 73, at A1 (observing concern over tobacco agreement); see also C.
tlement would place extensive restrictions on tobacco, critics note that the agreement places a heavy legal burden on the FDA to justify their control of nicotine. In particular, the FDA may only reduce nicotine and other harmful ingredients in cigarettes if it determines the following: that cigarettes will be less harmful, nicotine reduction is technologically feasible, and these altered cigarettes will not create a black market for cigarettes that do not meet the safety standard.

Ordinarily, to justify a rule, the FDA must demonstrate that it has not acted "arbitrarily or capriciously." Under the settlement, however, the agency would face a considerably stiffer burden in that it would have to prove that "substantial evidence" justify its actions. This new standard makes it far easier for the industry to challenge the FDA in court. Former FDA commissioner Kessler called the FDA's newly won ability to regulate nicotine "one of the most important public health victories of past several decades" but warned that "it would be a major mistake to water

---


137. *See* Koop, *supra* note 136, at 13A (asserting primary criticism of tobacco settlement); Freedman, *supra* note 73, at A1 (downplaying effect of court ruling giving FDA power to regulate tobacco). If approved by Congress, the settlement would require the following: industry payments of $368.5 billion over the next 25 years, a ban on billboard ads and vending machines; near-elimination of color ads; fines on the industry if youth smoking does not decrease by specific levels; FDA authority to regulate nicotine as a drug, including required disclosure of cigarette ingredients and the option to ban nicotine after 2009; and new warning labels that would take up 25 percent of the surface, with warnings such as "Smoking Can Kill You." *See* John Schwartz and Saundra Torry, *Tobacco Pact Calls for Strict Federal Controls*, WASH. POST, June 21, 1997, at A01 (listing terms of settlement). In return, the industry would receive the following: a dismissal of pending state lawsuits seeking recovery of health care costs and class action suits; immunity from class-action and similar lawsuits; and a legal damages maximum of $4 billion per year. *See* Levin, *supra* note 73, at A1 (providing industry benefits from settlement). If youth smoking does not reduce 42% within five years, the industry must pay a penalty of two billion dollars. *See* Koop, *supra* note 136, at 13A (criticizing aspects of settlement).

According to some legal experts, the immunity provisions violate due process of law and the right to a jury trial. *See* Susan B. Garland, *What May Stub out the Settlement*, BUS. WEEK, September 8, 1997 at 83 (discussing constitutional issues involving proposed settlement). In addition, former Surgeon General Koop warns that the tobacco industry, by raising the price per pack by ten cents, can easily cover the cost of certain penalties and make a considerable profit. *See* Koop, *supra* note 136, at 13A (explaining weakness of settlement term providing penalty for not reducing teen smoking); infra notes 154-58 and accompanying text (using Koop's figures to reveal flaws regarding certain aspects of settlement).


139. *See id.* (observing new FDA standard for justifying regulation).


141. *See id.* (stating new standard facilitates challenging FDA in court). Manufacturers may take the FDA to court and dispute their factual evidence. *Id.* In addition, the court may defer to the FDA's judgment only in those areas where the FDA has expertise. *Id.* FDA regulators openly admit their lack of expertise concerning the demand for contraband. *See id.* (showing public knowledge that FDA lacks expertise in shadowy field of contraband); *see also* supra note 138 and accompanying text (noting potential FDA challenges upon approval of settlement).
down or give away that authority."¹⁴² Kessler and former Surgeon General C. Everett Koop, serving as co-chairmen of a panel of health experts and advisers for the White House and Congress, will significantly effect the settlement’s prospects for approval.¹⁴³

B. Assessing the Settlement

Statistics show that the cigarette industry provides a clear case for regulation.¹⁴⁴ Given the continuous debate, however, no one measure has yielded an acceptable solution.¹⁴⁵ For some, the June 1997 settlement marked the long-awaited meeting of the minds, for others, the agreement permits the industry to follow the long tradition of cigarette manufacturers outflanking their opponents.¹⁴⁶ Although the settlement may appear as an advance in the right direction, its stranglehold on the FDA would allow the industry to avoid a significant amount of control.¹⁴⁷

The tobacco industry indeed has a long history of shrewdly turning what appears to be crushing defeat to its advantage.¹⁴⁸ Approval of the settlement would continue this trend by requiring the FDA to show substantial evidence of their justification for regulation.¹⁴⁹ This provision heightens the FDA’s burden of proof, resulting in a decrease in the scope of FDA’s regulatory authority.¹⁵⁰ When reducing nicotine levels, for example, the FDA must prove that it would not create significant demand for contraband.¹⁵¹ FDA regulators freely concede they do not have any

---

¹⁴². See John M. Broder, Former FDA Commissioner Calls Tobacco Deal a Retreat, SAN DIEGO UNION TRIB. June 22, 1997 at A6 (displaying concern of former FDA commissioner).

¹⁴³. See MEALY'S LITIG. REP.: TOBACCO, Koop-Kessler Committee Releases Official Report on Tobacco Settlement, July 17, 1997, at 4 (showing expertise and scrutiny involved in advising Clinton and Congress). The committee recommends that the FDA have explicit authority to regulate nicotine, including the right to phase out nicotine and remove ingredients that contribute to dependence. Id. The committee also states that any federal or state regulation of tobacco products should contain non-pre-emption provisions, thereby preserving all currently available causes of action in litigation, both civil and criminal. Id.

¹⁴⁴. See supra notes 3-5 and accompanying text (discussing smoking prevalence and its relation to death and disease).

¹⁴⁵. See supra notes 17-24 and accompanying text (providing brief history of tobacco regulation). Some commentators urge Congress to provide consistent measures of control at the federal level while others suggest that a focus on local initiatives would yield the greatest results. See id. (providing brief overview of regulation at local and federal level).

¹⁴⁶. See supra notes 135-38 and accompanying text (stating terms of recent settlement proposal); see also supra note 73 and accompanying text (noting industry ability to avoid enacted regulation).

¹⁴⁷. See supra notes 137-41 and accompanying text (discussing industry benefits upon approval of settlement).

¹⁴⁸. See Freedman, supra note 73, at A1 (discussing industry alertness to avoid regulation); supra note 73 and accompanying text (providing examples of industry sidestepping enacted regulation).

¹⁴⁹. See supra note 140 and accompanying text (discussing heightened standard of proof).

¹⁵⁰. See supra notes 140-41 (predicting new burden will limit FDA success).

¹⁵¹. See supra note 141 and accompanying text (noting situations where FDA will face problems
idea how to prove this. The industry can successfully challenge FDA evidence because courts will only defer to FDA findings where the FDA has expertise.

In addition, the agreement inadequately imposes penalties on the industry for failing to reduce youth smoking to certain levels in five years. Cutting youth smoking remains a top priority, however, the inconsequentiality of the punishment lessens the chance of industry compliance. As written, the settlement requires the industry to pay two billion dollars each year. This may appear to be a large sum, but in reality it works out to be merely eight cents per pack sold annually, three cents being tax-deductible. The industry could raise the price ten cents per pack, thereby covering the cost of the penalty while realizing a considerable profit.

Although the industry may enjoy certain advantages if Congress accepts the settlement, the elimination of numerous billboard ads and vending machines may reduce the prevalence of smoking among teenagers and curb the number of beginning smokers. If, however, FDA regulators cannot control nicotine as expected, the prospects for effectively decreasing the number of current smokers will diminish. Consequently, millions of smokers will remain addicted, and unfortunately, many smokers and nonsmokers alike will continue to contract various diseases. To the dismay of these affected individuals, the settlement would block off the most efficient avenues to recovery by granting the industry immunity from class-action and similar lawsuits.

with settlement terms).

152. See id. (acknowledging FDA lack of expertise in certain areas, thereby impacting amount of regulatory control).

153. See id. (showing likely result of FDA rulings if they lack substantial expertise).

154. See supra note 137 and accompanying text (mentioning weaknesses of settlement).

155. See id. (suggesting penalty may not actually harm industry); infra notes 156-58 and accompanying text (breaking down figures to reveal true ramifications of penalty).

156. See supra note 137 and accompanying text (outlining terms of settlement).

157. See Koop, supra note 136, at 13A (calculating figures to show minimal impact of penalty for not reducing youth smoking).

158. See id. (noting industry willingness to pay small price if addicting new generation possible).

159. See supra notes 7-16 and accompanying text (discussing smoking patterns among teenagers).

160. See supra notes 137-38 and accompanying text (noting heightened standard that settlement would require); see also supra notes 127-30 and accompanying text (highlighting industry manipulation of nicotine).

161. See supra note 4 and accompanying text (listing smoking related illnesses); supra notes 52-67 (discussing nicotine and addiction).

162. See supra note 137 and accompanying text (providing term of settlement which affords industry immunity from most future suits). By banning class-action and states’ lawsuits, the agreement eliminates the economies of scale which make it easier for an individual to attack the industry. See Freedman, supra note 73, at A1 (suggesting settlement affords industry immunity they sought all along). The tobacco industry, while spending approximately 600 million a year on legal fees, poses major difficulties to potential plaintiffs. See id. (noting difficulties involved in attempting to legally challenge tobacco industry).
industry’s willful manipulation of nicotine persists to surface, thus allowing manufacturers to escape future liability seems entirely premature. In *Coyne Beahm, Inc., v. United States Food & Drug Admin.*, the District Court of the United States for the Middle District of North Carolina concurred with the FDA’s findings and declared that the FDA had the statutory authority to regulate nicotine. This landmark decision provides tobacco opponents an unprecedented victory, however, the settlement impairs this ruling, thereby limiting the potential to ultimately subdue the industry. Although the attorneys general boldly faced “Big Tobacco” in their efforts to reach an amicable solution, they may have stripped themselves of their greatest weapons. The legal terms of the settlement, as evidenced by a subsequent rise in manufacturers’ stock prices, take away a court-won right and mark “not an advance but a retreat.”

V. CONCLUSION

The widespread documentation detailing the perils of tobacco consumption provides ample justification for regulation. Allowing current trends to continue would simply expand the grievous statistics and permit the industry to avoid responsibility for its unscrupulous practices. The *Coyne* decision gave anti-smoking proponents their long awaited answer to the future of tobacco regulation by establishing that the FDA has the statutory authority to regulate nicotine as a drug. The proposed settlement downplays many of the court’s findings and gives the industry yet another opportunity to sidestep regulatory control. The risks and dangers associated with smoking are too severe to warrant a lenient compromise.

David M. Forman

163. *See supra* notes 52 and 130 and accompanying text (showing evidence which indicates that industry may manipulate level of nicotine). By deliberately manipulating levels of nicotine, manufacturers intend to addict smokers. *See supra* note 129 and accompanying text (suggesting addiction takes away smoker’s ability to easily quit). Such behavior generates a considerable profit, therefore, the industry will continue this unscrupulous practice until the law forces it to do otherwise. *See* Koop, *supra* note 136, at 13A (asserting heart of tobacco industry lies in addiction). Although individuals may discover information that exposes the industry’s willful conduct, it “will be of scant use in the courtroom” if the industry receives immunity. *See* Freedman, *supra* note 73, at A1 (implying cigarette additives and nicotine provide individuals with strong causes of action against industry).


165. *See supra* note 135 and accompanying text (discussing ruling of federal court regarding FDA jurisdiction of nicotine).

166. *See supra* notes 17-24 (noting lack of previous federal control at federal level); *supra* notes 136-43 and accompanying text (explaining disadvantages of settlement).

167. *See supra* notes 135-43 and accompanying text (displaying settlement’s terms which limit previous ruling’s ramifications).
