The Politics of Reducing Tobacco Use Among Children and Adolescents: Why the Food and Drug Administration Cannot Regulate Tobacco and a Proposed Policy for States and Local Communities

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I. INTRODUCTION ...................................... 367

II. THE FDA ASSERTION OF JURISDICTION OVER TOBACCO PRODUCTS TO PLACE REGULATIONS FOR CHILDREN AND ADOLESCENTS ........................................... 369
   A. An Overview of the FDA Proposed Rule for Tobacco Products .................................. 369
   B. Statistics Regarding Tobacco Use Among Children and Adolescents ......................... 372
   C. An Analysis of the FDA’s Proposed Jurisdiction Over Tobacco Products: How the FDA is Making Their Case ............................................. 377
   D. FDA’s Legal Argument for Authority ................................................................. 378

III. PROBLEMS WITH THE FDA’S UNILATERAL ATTEMPT TO ASSERT JURISDICTION OVER TOBACCO PRODUCTS ....................................................... 382
   A. Constitutional Problems ...................................................................................... 382
   B. Federalism Principles ......................................................................................... 387

IV. HOW THE TOBACCO INDUSTRY CONTROLS THE POLITICAL AGENDA FOR TOBACCO CONTROL INITIATIVES ...................................................... 390
   A. Federal Government .......................................................................................... 390
   B. State Governments .......................................................................................... 393

V. A STATE AND LOCAL POLICY TO SUBSTANTIALLY REDUCE TOBACCO USE AMONG CHILDREN AND ADOLESCENTS .......................... 395

VI. CONCLUSION .................................................. 400

I. INTRODUCTION

On August 10, 1995, President Clinton announced broad executive action to protect children and adolescents from the dangers of tobacco products.1 Through executive authority, the President is attempting to sharply restrict the

advertising, promotion, distribution, and marketing of tobacco products for children and adolescents by authorizing the Food and Drug Administration (FDA) to seek jurisdiction over tobacco products as "drug delivery devices." The FDA is proposing new federal regulations to govern the sale and distribution of tobacco products to children and adolescents in order to address the serious public health problems caused by the use of and addiction to these products. Tobacco product use among children and adolescents is a health epidemic problem. It is such a problem that FDA Commissioner Dr. David Kessler in a March, 1995 speech at the Columbia University School of Law labeled smoking a "pediatric disease."

This paper will reveal that although the FDA has a compelling argument from a public health point of view to regulate tobacco products, the proposed federal rule is beyond the scope of the FDA's authority. The FDA cannot unilaterally assert jurisdiction over tobacco products in order to implement restrictions for children and adolescents without specific Congressional action. Instead, Congress has specifically delegated such regulatory authority to the states. Moreover, the proposed rule lacks necessary enforcement mechanisms to adequately keep tobacco products out of the hands of children and adolescents.

The primary purpose of this note is to illustrate that the FDA's proposed rule is beyond its jurisdiction and contrary to the intent of Congress. Special emphasis is given to how the tobacco industry controls the political agenda for tobacco control initiatives. Tobacco control laws similar to restrictions placed

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2 Id.

3 See infra note 58 and accompanying text.


5 "Tobacco products" means nicotine-containing cigarettes and smokeless tobacco products for purposes of this paper. See Id. at 41322 (commenting that proposed rules would not apply to pipe tobacco or cigars because current evidence does not conclusively prove that these products are within the scope of the FDA's proposed authority and most children and adolescents use cigarettes and smokeless tobacco products).

6 Id. at 41314.


on alcoholic beverages sales should be enacted at the state and local level. Additionally, local governments should be permitted to have the flexibility to enact stricter tobacco control initiatives without being preempted by state law.

The effort to keep tobacco products out of the hands of children and adolescents should be a cooperative federalism approach with each level of government having its own responsibility. The federal government would provide guidance and funding to states through the Synar Amendment rule, and the states and local governments would enact and enforce aggressive tobacco control initiatives. Because states and local governments are closest to the problem of tobacco use among children and adolescents, states and local governments are best suited to resolve the problem. This federalism approach to tobacco control for children and adolescents is already possible under existing federal statutes without additional federal intrusion. The strength of the tobacco industry’s lobby, however, has prevented additional practical tobacco control policy for children and adolescents from being enacted.

Following the introduction of this note, Section II provides an overview and an analysis of the FDA’s assertion of jurisdiction over tobacco products. This section includes alarming statistics on tobacco use among children and adolescents and the tobacco industry advertising. Section III of the paper addresses the problems of the FDA’s unilateral attempt to assert jurisdiction over tobacco products in constitutional and federalism contexts. Section IV reveals how the tobacco industry controls the political agenda at the federal and state level for tobacco control initiatives through sophisticated lobbying efforts and campaign contributions. Finally, Section V provides a state and local policy to substantially reduce tobacco use among children and adolescents and an explanation on why these methods are preferable over other regulatory schemes.

II. THE FDA ASSERTION OF JURISDICTION OVER TOBACCO PRODUCTS TO PLACE REGULATIONS FOR CHILDREN AND ADOLESCENTS

A. An Overview of the FDA Proposed Rule for Tobacco Products

The primary objective of the proposed rule is to reduce the death and disease caused by tobacco products. The goal of the proposed rule is to achieve one of the objectives of "Healthy People 2000:" namely to reduce tobacco use among children and adolescents by half by the year 2000. Furthermore, if the objective of the proposed rule is not met within seven years after publication of a final rule, the FDA can take additional regulatory initiatives in order to

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10The Healthy 2000 Report discussed national health promotion and disease prevention objectives in this country. It was facilitated by the Institute of Medicine of the National Academy of Sciences, with the help of the U.S. Public Health Service, and included participation of almost 300 national membership organizations and all State health departments. See 60 Fed. Reg., supra note 4.

11Id. at 41321.
achieve the Healthy 2000 goal. Therefore, if the number of children and adolescents using tobacco products is not reduced by half within seven years after implementation of the rule, then additional restrictions may be imposed by the FDA. This is an aggressive goal especially through the provisions of the FDA’s proposed rule which are open-ended. However, the key component to reduce tobacco use among children and adolescents, as further discussed in Section V, is to substantially reduce children and adolescents’ access to tobacco products.

The proposed federal rule addresses two areas of regulations. First, the proposed rule makes tobacco products less accessible to children and adolescents through greater sales restrictions, and second, it places restrictions on labeling and advertising to help reduce the appeal of tobacco products to children and adolescents.

The proposed rule specifically includes the following provisions: (1) establish eighteen (18) years of age as the minimum age for the purchase of tobacco products; (2) eliminate the use of cigarette vending machines, free samples, mail-order sales, and self-serve displays; (3) require retailers to comply with certain conditions regarding tobacco sales; (4) limit the advertising and labeling to which children and adolescents are exposed to a text-only format; (5) ban the sale or distribution of brand-named tobacco items (6) restrict sponsorship of events to the corporate name only; and (7) require tobacco manufacturers to create and fund a national public education campaign aimed at persons under the age of eighteen to counter the positive image of tobacco product advertisements.

The action taken by the Clinton Administration and the FDA has been widely hailed as the most important step in tobacco control since the Surgeon General’s 1964 Report on Smoking and Cancer. On the day of the proposed rule announcement, the tobacco industry and various advertising and publishing associations in response to the proposed rule filed separate lawsuits. The lawsuits seek a declaratory judgment that FDA’s assertion of jurisdiction over tobacco products is exceeding the agency’s statutory authority, usurping the authority of Congress and violating the First Amendment.

12 Id. at 41375 (citing proposed 21 C.F.R. § 897.44).

13 Proposed 21 C.F.R. § 897.14 “Additional Responsibilities of Retailers” would require all retailers and their employees to verify proof of the purchaser’s age, require face-to-face sales, and prohibit retailers or their employees from opening a tobacco product package to sell or distribute a single cigarette or any quantity from the package. See 60 Fed. Reg., supra note 4 at 41315.

14 Id. at 41314.

15 Christina Kent, Tobacco-Control Coup. Proposed FDA Regulation of Tobacco Products, AM. MED. NEWS, Aug. 18, 1995, at 1 [hereinafter Kent, Tobacco Control Coup]. The Smoking and Health, Report of the Advisory Committee to the Surgeon General of the Public Health Service (1964) claimed that smoking had the potential to cause cancer of esophagus, larynx, lung, and mouth, as well as chronic bronchitis, emphysema, heart disease and other illnesses.
Amendment. The lawsuits, filed in federal district court in Greensboro, North Carolina, are currently pending.

Originally, the proposed rule called for a ninety-day comment period. On October 16, 1995, however, the FDA extended the comment period for the proposed rules to January 2, 1996. The result of the extension was to provide a comment period of more than 140 days on the notice. Now that the comment period has concluded, the FDA under the rulemaking procedures, must review and develop a final rule based on the recommendations and comments received. On the final day of comment, the tobacco industry submitted 47,000 pages of documents which contain arguments on why it is illegal for the FDA to seek jurisdiction over tobacco products, while also emphasizing that children and adolescents should not use or have access to tobacco products. Additionally, the tobacco industry claimed that the FDA's proposed rule is a transparent first step in pursuit of its real agenda which is a ban on the sale of cigarettes to adults. No timetable is set to issue a final rule.

The battle between the FDA, who is assisted by tobacco-control groups, and the tobacco industry is currently being waged for the "hearts and minds"


18Extension of Comment Period, 60 Fed. Reg. 53560 (1995); (extending the comment period in response to a 180-day extension request by the Tobacco Institute; Brown & Williamson Tobacco Corp.; Liggett Group; Philip Morris, Inc.; R. J. Reynolds Tobacco Co.; the Smokeless Tobacco Council, Inc.; Conwood Company, L. P.; Whisher Tobacco Co.; National Tobacco, L.P.; Pinkerton Tobacco Co.; and the U.S. Tobacco Co; a 90-day extension request by the Food Marketing Institute; and a 9-month extension request by the Cigar Association of American, Inc.).

19News Conference, Tobacco Industry’s Comments On The FDA Proposed Regulation of Tobacco Products, Jan. 2 1996 [hereinafter Tobacco Industry News Conference] (transcript available in LEXIS)(commenting among other arguments that no purpose can justify a federal agency’s unauthorized intrusion into an area over which Congress and the States already have jurisdiction and responsibility).

20Id.; see also 60 Fed. Reg., supra note 4 at 41355 (claiming the FDA could implement a total ban of tobacco products if the agency would regulate tobacco under the new drug regulations).


22See Christina Kent, Battle Over FDA Tobacco Regulations: Youth and Smoking, AM. MED. NEWS, Nov. 6, 1995 at 3.[hereinafter Kent, Battle Oter] (the Coalition on Smoking OR Health which consists of the American Cancer Society, American Heart Association, and the American Lung Association has joined with the AMA, American Academy of
of the public for support of their own agendas. A number of marketing techniques are being used by both sides to get their message across to the public to contact the FDA, members of Congress, and write letters to the editors of newspapers. Also, as one of his seven challenges in his 1996 State of Union Address, President Clinton challenged the American people to continue to push to restrict tobacco use among children and adolescents.

B. Statistics Regarding Tobacco Use Among Children and Adolescents

More than 430,000 individuals die each year from illness related to tobacco use. Tobacco products cause more deaths each year than alcohol, guns, AIDS, murders, suicides, illegal drugs, automobiles and fires combined. It is the most preventable method of death. Tobacco use costs our nation fifty billion dollars in direct health care costs and an estimated forty-five billion dollars in indirect costs. Approximately three million children under the age of eighteen smoke cigarettes every day and one million adolescent males use smokeless tobacco. Moreover, every day three-thousand children and adolescents become regular new smokers and one-thousand will eventually die as a result of smoking. The younger an individual begins to use tobacco products, the more likely that individual will become a heavy user of tobacco products as an adult. This is the main reason why FDA Commissioner Kessler labeled tobacco use as a pediatric disease. If an individual begins using tobacco products in their youth, there is greater likelihood the habit will continue into

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Pediatrics and 125 other organizations to form the "Campaign for Tobacco Free Kids"); see also John Schwartz, Group Targets Tobacco Use Among Youth; Association-Backed Center Shares Cause With FDA, WASH. POST, Feb. 12, 1996, at 17 (discussing the new National Center for Tobacco-Free Kids organization which was created from a Robert Wood Johnson Foundation grant).

Tobacco industry ad in newspapers are inviting readers to call a toll-free number (800 366-8441) to receive a kit to teach young people how to resist peer pressure to smoke. Tobacco opponents are using the same marketing tools. For example, the Campaign for Tobacco Free Kids' ads in major newspapers are urging readers to write to the FDA and call (800) 284-KIDS for information kits, see Kent, Battle Over, supra note 22.


Melissa Hough Savage, Selling Tobacco To Minors, NAT'L. CONF. STATE LEGISLATURES LEGISBRIEF 2 (Sept. 1994).

Office on Smoking and Health, Centers for Disease Control and Prevention, State Tobacco Control Highlights-1996 (1996) at foreword v.


Id.

adulthood. It is estimated that children and adolescents use anywhere from 5,160,000 to 9,470,000 packs of cigarettes each year.\textsuperscript{31} According to a study on youth risk behavior, nearly seventy percent of all high school students have tried cigarettes, and nearly one-third of all high school students used cigarettes within thirty days of the survey.\textsuperscript{32} The statistics show that a child’s or adolescent’s simple experimentation with tobacco products can lead to long-term addiction. As further evidence, eighty-two percent of adults who have used tobacco products began prior to their eighteenth birth date.\textsuperscript{33} Without question, children and adolescents are heavy users of tobacco products.

Even though every state prohibits the sale of tobacco products to persons under the age of eighteen,\textsuperscript{34} these state laws are not aggressively enforced.\textsuperscript{35} As a result, children and adolescents have easy access to tobacco products. A review of thirteen studies of over-the-counter sales found that, on average, children and adolescents were able to buy tobacco products sixty-seven percent of the time.\textsuperscript{36} Also, nine studies which examined illegal vending machine sales found that children and adolescents were able to purchase tobacco products on average eighty-eight percent of the time.\textsuperscript{37}

Tobacco products are sold at almost every retail store and are visible almost everywhere despite an advertising ban on television and radio.\textsuperscript{38} In fact, tobacco products are one of the most advertised products in the country.\textsuperscript{39} Further, the tobacco industry sponsors many sporting events. Sponsorship of events such as auto races and tennis tournaments associate tobacco products


\textsuperscript{32}U.S. Dep’t of Health and Human Servs., \textit{Youth Risk Behavior Surveillance-United States}, 1993, 44 MORBIDITY & MORTALITY WKLY REP. 8 (1995); see also President’s News Conference, supra note 1 (stating that one-third more eighth grade students and one-quarter more tenth grade students are users of tobacco products than four years ago and one out of five high school seniors is a daily user of tobacco products).

\textsuperscript{33}Surgeon General Report, 1994, supra note 7, at 65.

\textsuperscript{34}U.S. Dep’t of Health and Human Servs., \textit{State Laws on Tobacco Control-United States}, 1995, 44 MORBIDITY & MORTALITY WKLY REP. 7 (1995)[hereinafter State Laws].

\textsuperscript{35}Id. at 16 (table 3A shows that only 35% of the states have designated an enforcement authority: Connecticut, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, New Hampshire, New Mexico, New York, Oklahoma, Oregon, South Dakota, Tennessee, Vermont, Virginia, and West Virginia).

\textsuperscript{36}Surgeon General Report, 1994, supra note 7, at 249.

\textsuperscript{37}Id.


\textsuperscript{39}Surgeon General Report, 1994, supra note 7, at 160.
with excitement and thus promotes tobacco product use. For instance, auto racing is a nonstop cigarette advertisement despite the ban of tobacco advertisement on television. A review of the ninety-minute NBC telecast videotape of the 1989 Marlboro Grand Prix had 5,992 visual and verbal mentions of the cigarette brand name and logo. As noted earlier, the proposed rule would ban such sponsorship of events to corporate name only, thus, eliminating sponsor named events such as the Marlboro Grand Prix. Under the proposed rule, the event would be required to be renamed the Phillip Morris Grand Prix.

The tobacco industry spent $6.2 billion on advertising, promotions, and marketing of tobacco products in 1993. Many of the tobacco industry promotional items such as hats and shirts find their way into the hands of children and adolescents. According to a national phone survey of children age twelve to seventeen, eleven percent of these children surveyed owned at least one promotional item from the tobacco industry. Also, through mail-order promotions, the tobacco industry has built a large mailing list of tobacco users. In the same national survey, 7.6 percent of the children surveyed received tobacco industry’s promotional mailing directly addressed to them. It is estimated that there are 1.6 million teenagers on the tobacco industry’s mailing lists.

A number of studies reveal that the tobacco industry markets their products towards children and adolescents. A recent study published in the Journal of the National Cancer Institute found that marketing of tobacco products is primarily responsible for the increase in the use of tobacco products among children and adolescents. Children and adolescents are more likely to be influenced by advertising and promotion than by peer pressure. The tobacco industry, however, claims the study to be poorly premised and politically

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4160 Fed. Reg., supra note 4, at 41315 (citing Federal Trade Commission, Report to Congress for 1993, Pursuant to the Federal Cigarette Labeling and Advertising Act, 1995) at Table 3D (showing that the tobacco industry spent $2.6 billion on financial incentives to consumers, $1.9 billion on advertising and promotional activities, and $1.6 billion on retailer sale enhancement allowances).


43Id.

44Id.


46Gidding, supra note 45, at 23.
motivated. Instead, the tobacco industry claims the most influencing factor for children and adolescents to begin tobacco product use is a same sex friend. One notable study on tobacco advertising and children revealed that thirty percent of children age three and ninety-one percent of children age six could associate the "Joe Camel" cartoon figure with cigarettes. Two hundred and twenty-nine children from preschools in Augusta and Atlanta, Georgia were instructed to match logos with one of twelve products pictured on a game board which included children products such as McDonald's and Nike; adult products such as Ford and NBC; and cigarette brands such as Camel and Marlboro. The study design was based on the well-accepted market research concept of advertisement recognition. In the study, the children demonstrated high rates of logo recognition and recognition levels increased with age. Yet when the Federal Trade Commission, which ensures advertising of tobacco products is fair, was asked to ban Joe Camel, the commission declined. The commission claimed a lack of evidence existed to determine that the ad campaign directly caused children and adolescents to use tobacco products.

On the other hand, the tobacco industry counters against studies of advertising and tobacco use among children and adolescents with global evidence which proves no correlation. For instance, both the countries of Norway and Finland have had total advertising bans on tobacco since 1975 and 1978, respectively. The bans, however, have had little or no effect on tobacco use among children and adolescents. In Finland, the rate of tobacco use among teenagers has not significantly changed, and in Norway the number actually increased since the enactment of the advertising bans. For example, the Finland proportion of daily smokers among boys age fourteen to eighteen decreased from twenty-seven percent prior to the ban to twenty-five percent.


48Id. at 202.

49Sheryl Stolberg, Joe Camel Leads the Pack in Lighting Up Controversy, L.A. TIMES, Aug. 21, 1995, at 1 (citing a Center for Disease Control and Prevention report that prior to the introduction of Joe Camel in 1988, an estimated three percent of teenagers and 4% adult smokers used Camel cigarettes, however, five years after the introduction of the Joe Camel ad campaign, the percentage of adults remained the same while teenage smokers increased their use to 13% in 1995).

50P.M. Fischer, et al., Brand Logo Recognition by Children Aged 3 to 6 Years, Mickey Mouse and Old Joe Camel, 266 JAMA 3145 (1991).

51For a commentary on the Federal Trade Commission's refusal to ban "Joe Camel," see John Harrington, Up In Smoke: The FTC's Refusal To Apply The "Unfairness Doctrine" To Camel Cigarette Advertising, 47 FED. COMM. L.J. 593 (Apr. 1995).

52Harry Berkowitz, Joe Camel cigarette ads won't be curbed Tobacco firms win rare victory, ATLANTA J. & CONST., June 2, 1994, at 1; Cf. Stolberg, supra note 49, at 1 (citing a tobacco industry study which duplicated Fischer's Joe Camel study found that although 6-year olds did recognize Joe Camel, 96% of the children disapproved of smoking).

53DAILY REP. EXECUTIVES, supra note 47.
in 1993. For girls the same age, the number decreased from twenty-six percent prior to the ban to twenty-three percent in 1993. The smoking rate of Norwegians age sixteen to eighteen, on the other hand, increased between 1990 and 1995 from thirty percent to forty-two percent.

Studies have also shown far-reaching public support for restrictions on children and adolescent access to tobacco products. One national survey published in October, 1994, showed virtually all respondents believed tobacco use by children and adolescents is a "very serious" or "somewhat serious" problem. Additionally, the survey revealed popular support existed for vending machine restrictions, imposition of fines on sellers, licensure of tobacco product vendors, ban of advertising, and an increase of the cigarette excise tax. Similar results were found in the 1990 Smoking Activity Volunteer Executed Survey. This adult survey conducted in Arizona, Michigan, Pennsylvania, and Texas found that more than eighty-two percent of the respondents believed that stronger laws need to be enacted to prevent children and adolescents from purchasing tobacco products. Additionally, more than eighty-six percent believed that existing laws should be more strictly enforced.

According to FDA Commissioner Dr. David Kessler, statistics and studies like those above were part of the reason for the FDA's assertion of jurisdiction over these products to place restrictions for children and adolescents. The proposed rule, as announced by President Clinton, is based on the best available scientific evidence and findings which show that tobacco products are harmful, addictive, and marketed to young children and adolescents.

54 Id.
55 Id.
56 Id.
57 William J. Bailey, et al., A National Survey of Public Support for Restrictions on Youth Access to Tobacco, 64 J. SCH. HEALTH 314 (Oct. 1994)(finding that survey respondents believed smoking by children to be "very serious" (64.3%) and "somewhat serious" (29.3%)and "not at all serious" (0.5%)).
58 Id. at 315.
59 Stephen E. Marcus, et al., Public Attitudes about Cigarette Smoking: Results from the 1990 Smoking Activity Volunteer Executed Survey, 109 PUB. HEALTH REP. 125 (Jan./Feb. 1994)(citing that respondents favored prohibiting the distribution of free tobacco products (73%); banning advertising in print (60%); and banning sponsorship of sporting events or advertising at these events (between 49 & 59%).
60 Id.
61 FDA Commissioner David Kessler, Address on the President's Initiative to Curb Smoking by Teenagers at St. Jude's Children's Hospital, Memphis, Tenn. (Oct. 20, 1995) (transcript available in LEXIS).
62 The proposed rule was based upon the findings of the American Medical Association, the American Cancer Society, the American Heart Association, the Ameri-
C. An Analysis of the FDA’s Proposed Jurisdiction Over Tobacco Products: How the FDA is Making their Case

In determining whether tobacco products may be regulated by the FDA, the agency put together a compelling case that the nicotine in tobacco products is a drug and that these products are drug (nicotine) delivery devices. In a 326-page document which is located in the appendix of the proposed rule, the FDA addresses the issue of its asserted jurisdiction over "nicotine-containing tobacco products." The document is the result of comprehensive investigative and legal analysis which the FDA claims supports a finding that the nicotine in tobacco products is a drug and these are drug-delivery devices within the meaning of the Federal Food, Drug, and Cosmetic Act.

What is most interesting about the FDA’s assertion of jurisdiction comes from the use of internal documents of the tobacco industry. In essence, the FDA is using the tobacco industry’s own words to determine that tobacco products are drug delivery devices. For example, in an internal tobacco industry memorandum, a tobacco company general counsel stated:

Moreover, nicotine is addictive... We are, then, in the business of selling nicotine, an addictive drug.

The tobacco industry’s internal documents also reveal that the industry intended to produce nicotine delivery systems. In 1972, a Philip Morris executive said:

[t]hink of the cigarette pack as a storage container for a day’s supply of nicotine... [t]hink of the cigarette as a dispenser for a dose unit of nicotine:... [t]hink of a puff of smoke as the vehicle of nicotine... [s]moke is beyond question the most optimized vehicle of nicotine, and the cigarette the most optimized dispenser of smoke.

In another internal document, published in the N.Y. Times, an R.J. Reynolds executive proclaimed:

In a sense the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceu-
tical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects.67

The foundation for jurisdiction over tobacco products is taken directly from the tobacco industry's own words. There are striking similarities to the tobacco industry's internal comments and the FDA's legal analysis to assert jurisdiction over tobacco products.

In response, the tobacco industry has asserted that the FDA has utilized improper methods to reveal that the agency has jurisdiction over tobacco products. The industry claims the entire rule making has been fatally tainted by the agency's reliance on secret data provided by biased sources.68 The tobacco industry also has claimed that the FDA has utilized confidential documents which include many unpublished studies and other materials which the FDA refuses to disclose.

While the tobacco industry has not outright disputed the published internal documents, the industry has downplayed their impact which is consistent with the tobacco industry's usual response to such documents. For example, internal tobacco documents have been used in prior court proceedings concerning health-related suits, and according to a Philip Morris spokesperson, "when documents that are sensationalized in the press find their way into the courtroom, juries have failed to find them to be evidence of wrongdoing."69

D. FDA's Legal Argument for Authority

According to the FDA, the results of their inquiry of nicotine support a finding that because nicotine in tobacco products is "intended to affect the structure or function of the body and it achieves its intended effects through chemical action within the human body"70 it may be regulated as a device under the Federal Food, Drug, and Cosmetic Act.71 The FDA is labeling cigarettes and smokeless tobacco as "drug-delivery devices." The FDA is asserting that tobacco products, as a drug-delivery system, purpose is to deliver nicotine to the body in a method which is most readily absorbed by the consumer.72 Obviously, the FDA's contention is not without criticism, especially by the tobacco industry. One commentator called the labeling of

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68 Tobacco Industry News Conference, supra note 19.


70 60 Fed. Reg., supra note 4, at 41521.

71 Id. (citing 21 U.S.C.S. §§ 321(g)(1)(C), 321(h)(3) as authority for the regulation of tobacco products).

72 Id.
tobacco products as nicotine delivery devices is like labeling Scotch as an ethanol-delivery device or coffee as a caffeine-delivery device.73

Under the proposed rule, tobacco products would be regulated as a combination product under the device regulations, not solely as a drug.74 Title 21 Code of Federal Rules 3.2(e) provides the definition of combination product. It provides in pertinent part:

(e) Combination product includes:

(1) a product comprised of two or more regulated components, i.e., drug/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed . . . .

According to the FDA, tobacco products are combination products over which the FDA has discretion to regulate using drug authorities, device authorities, or a combination of both authorities pursuant to the Safe Medical Device Act of 1990 which amended the Food, Drug, and Cosmetic Act. The 1990 Act recognized the need for additional regulations of products that constitute a combination or a drug, device or biological product.75 The 1990 Act, codified at 21 U.S.C.S. § 353 (g) governs these regulations. 21 U.S.C.S. § 353(g) provides in part that:

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product.

On the other hand, if the FDA were to regulate tobacco products pursuant to the new drug authority, tobacco products would not be approved, and accordingly, the FDA could remove tobacco products from the market.76 The


75Id. at 41521(citing 21 C.F.R. § 3.2(e) (1994) as authority to regulate tobacco products).

76Id. at 41348 (authorizing tobacco products removal pursuant to 21 U.S.C.S. 331(d) (Law. Co-op 1993) which prohibits the introduction or delivery for introduction into
"new drug" provisions would require that tobacco products are generally recognized as safe and effective. 21 U.S.C.S § 321 (p)(1) defines "new drug" in pertinent part as:

Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . .

According to the FDA, tobacco products would not be considered safe and effect under the agency's new drug application process. Thus, the agency would be required to remove the products from the market because the evidence on tobacco products' effects on health proves that the products are not safe for its intended use. 21 U.S.C.S. § 355 (a) governs the new drug provisions which provide in pertinent part that:

Necessity of effective approval of application. No person shall introduce or deliver into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drugs.

The FDA, however, believes that a total ban on all tobacco products would not be in the best interests of the public health at this time. Nevertheless, the FDA believes that because of the dangerous health consequences from using tobacco products, aggressive initiatives must be taken to prevent future generations from using and becoming addicted to tobacco products.

Instead of a complete ban on tobacco products, the FDA proposes to make these products subject to regulation of the Federal Food, Drug and Cosmetic Act's device authorities to allow the continued marketing of the products. The Act's definition of device is statutory and the courts have upheld a broad construction of its meaning. The FDA is attempting to include tobacco

interstate commerce of any article without meeting approval of new drug standards. 21 U.S.C.S. 355(a) (Law. Co-op 1993) governs new drug applications which must be safe for its intended use).

77 id. at 41348-49 (citing reasons for not banning tobacco products as: (1) high addiction rates and difficulties to quit may cause adverse health consequences; (2) current health care system may not be able to provide adequate treatment for withdrawal; and (3) not unreasonable to assume a black market or smuggling would develop).

78 60 Fed. Reg. at 41350.

79 id. at 41349.

80 See e.g., United States v. An Undetermined Number of Unlabeled Cases 21 F.3d 1026, 1028 (10th Cir. 1994)(the Act regulates as a "device" an article intended for use in diagnosis regardless of whether medical treatment will follow); United States v. 22 Rectangular Devices, 714 F. Supp. 1159, 1162 n.7 (D. Utah 1989)(listing examples of devices such as facial exerciser, electric acupuncture instrument, phonographic records
products within the meaning of device. The Medical Device Manufacturers' Association, however, has submitted a statement in opposition to the proposed rule. The Medical Device Manufacturers Association represents one hundred small to medium sized domestic medical device manufacturers. In fact, ninety-eight percent of the medical device industry consist of companies with less than five hundred employees and seventy-two percent have less than fifty employees.

In terms of tobacco products, the FDA is claiming that these products function like other drug delivery systems such as pre-filled inhalers, transdermal patches, and metered-dose inhalers. The tobacco product contains the drug nicotine and is used to deliver the drug to the area of the body where it will be absorbed. The area is the lungs for cigarettes, while for smokeless tobacco the area is the mouth. After the drug is received into the body, the cigarette butt or the tobacco material is depleted of the drug and then discarded by the user. The FDA asserts that "only the nicotine delivered by these products achieves its primary intended purpose by chemical action in or on the body." Based on the above analysis, the FDA is proposing to regulate tobacco products as "restricted devices" in order to place restrictions on tobacco products. The restricted device authority provision allows the FDA to issue regulations restricting the sale, distribution, or use of a device "if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." The FDA has determined that there is no reasonable assurance of the safety and effectiveness of tobacco products and that additional restrictions are needed to prevent a new generation of children and adolescents from becoming addicted to tobacco products. The regulations are specifically aimed at children and adolescents because, as noted earlier, the use of tobacco products usually begins during childhood.

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81 Tobacco Industry News Conference, supra note 19 (discussing the Medical Device Manufacturers' Association of American's statement).

82 A nicotine patch is an example of a transdermal patch. The difference between nicotine patches and tobacco products is there are therapeutic claims made in the marketing of the patches which allows for FDA regulation. No similar claim is made for tobacco products. Id. Nicotine patch is currently available as an over-the-counter-drug.

83 60 Fed. Reg. at 41347.

84 Id.

85 Id. at 41349.

86 Id. (citing, Safe Medical Devices Act of 1990, § 520(e)(1)(B)).

87 60 Fed. Reg. at 41350.
Accordingly, the FDA is proposing to regulate tobacco products pursuant to its restricted device authority which will afford the most appropriate and flexible mechanism for regulating these products and fits better with the aims of the proposed rule.  

In response, the tobacco industry claims that the FDA, through jurisprudential gymnastics, has concocted an unauthorized and unprecedented structure under which tobacco products are drugs but will be regulated as medical devices. Furthermore, the tobacco industry has argued that the nicotine in the average cigarette today is lower than ever. The tobacco industry cites that the average nicotine level in cigarettes decreased from 2.6 milligrams to 0.89 milligrams from 1954 to 1993.

It should be noted that no where in the FDA's use of statutory authority is there any expression of congressional intent to have tobacco products within the meaning of devices or to have the FDA assume regulatory authority over tobacco products. However, courts must interpret the Federal Food, Drug, and Cosmetic Act broadly to aid in protecting public health.

III. PROBLEMS WITH THE FDA'S UNILATERAL ATTEMPT TO ASSERT JURISDICTION OVER TOBACCO PRODUCTS

A. Constitutional Problems

Article One, Section Seven, Clause Two of the U.S. Constitution provides that "[e]very Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes law, be presented to the President of the United States" who may veto the bill or approve it. This provision and Clause Three, make-up the bicameralism and presentment requirements for law-making under the U.S. Constitution. The FDA asserts that new evidence reveals that nicotine is a drug and tobacco products are drug delivery devices. The FDA, therefore, may regulate tobacco products under existing statutes. Congress, however, has never specifically delegated such regulatory authority to the FDA through legislation. The issue of whether FDA should have jurisdiction to regulate tobacco products has been raised numerous times in Congress, but Congress has determined each and every time that the agency should not have

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88 Id. at 41347.
89 Tobacco Industry News Conference, supra note 19.
91 See U.S. v. Undetermined No. of Unlabeled Cases, 21 F.3d 1026 (10th Cir. 1994); U.S. v. Two Plastic Drums, More or Less of an Article of Food, Labeled in Part: Viponte Ltd. Black Currant Oil Batch No. BOOSF 039, 761 F.Supp. 70, affirmed 984 F.2d 814, rehearing denied (7th Cir. 1991).
92 U.S. CONST. art. I, § 7, cl. 2.
In fact, Congress has never delegated any type of tobacco regulatory activities to the FDA, including reporting responsibilities. In delegating aspects of tobacco regulatory authority to various agencies, Congress has taken specific action through legislation. Congress has never given any duties to the FDA over tobacco products. Although Congress has delegated broad authority to the FDA over drugs, devices, and combination products, the language and intent was never to include tobacco products. In fact, according to the 1989 testimony of FDA Chief Counsel Thomas Scarlett before a Subcommittee of the House Appropriations Committee on the possible regulation of tobacco products under the Federal Food, Drug and Comestic Act, he asserted that "the act draws the lines and we have to respect them. . . . What is fairly important in FDA law is whether a product has a therapeutic purpose, at least if you are talking about something that might be a drug."

The absence of Congress delegating authority to the FDA is one of the main arguments claimed by the tobacco industry against the proposed rule. The tobacco industry claims that when the FDA asserted jurisdiction, it was an illegal power grab on the part of that Agency. Further, the federal courts have previously agreed that the FDA has no jurisdiction over tobacco products absent a therapeutic claim by the tobacco industry. The tobacco industry has never made such a claim. In ASH v. Harris, the Federal District of Columbia


94 See e.g., 26 U.S.C.S. § 5701(b) (Law. Co-op. 1995) (authorizing the Internal Revenue Service to implement cigarette sales tax collection); 15 U.S.C.S. § 1335a (Law. Co-op. 1993) (authorizing the Secretary of Health and Human Services to review list of ingredients in tobacco products and report to Congress on health effects from those added ingredients); 15 U.S.C.S. § 1333(c) (Law. Co-op. 1993) (authorizing the Federal Trade Commission to implement the congressional mandated warnings on tobacco products labels); 15 U.S.C.S. § 1341(a) (Law. Co-op. 1993) (authorizing the Department of Health and Human Services to conduct extensive research on the health effects of tobacco product use report findings to Congress); 15 U.S.C.S. § 1337(b) (Law. Co-op. 1993) (authorizing the Federal Trade Commission to submit an annual report to Congress on cigarette advertising practices and methods which may include recommendations to restrict such advertising); 15 U.S.C.S. 1341(b) (Law. Co-op. 1993) (requiring the Interagency Committee on Smoking and Health to submit biennial reports to Congress on activities undertaken to inform the public about tobacco product use risks).

95 Hearings before the Subcomm. on Rural Development, Agriculture, and Related Agencies, of the House Comm. on Appropriations, 100th Cong., 2d Sess., part 8, at 409 (1989).

96 Tobacco Industry News Conference, supra note 19.

97 ASH v. Harris, 655 F.2d 236 (D.C. Cir. 1980).

98 Id.
Appellate Court upheld a ruling that the FDA does not have jurisdiction over cigarettes containing nicotine and that proper deference should be given to Congress. The case arose from the Action on Smoking OR Health’s petition which challenged the FDA’s refusal to assert jurisdiction over cigarettes containing nicotine as a drug or device.

Even FDA Commissioner Kessler had the long-standing position that the agency could not regulate tobacco products without direction from Congress. However, the evidence revealed from internal documents of tobacco industry may show misrepresentations on their part and aid the FDA’s argument. Although this may help justify the FDA’s assertion over tobacco products, it is not enough. Congressional action is still required to have the FDA assert jurisdiction over tobacco product. If the FDA were able to assume jurisdiction without approval by Congress, it would dampen the integrity of the Constitutional framework of our system of government. One member of Congress, in response to the proposed rule, argued that “a precedent must not be set whereby a federal bureaucrat [Commissioner Kessler], in contravention of the Constitution, can carve out for himself and his agency, rights and prerogatives specifically reserved by the Constitution to the Congress and the states.”

In his announcement of the executive action and in repeated follow-up commentary, President Clinton has said that he would prefer if Congress were to meet the same goals through legislation, thus, rendering the lengthy rulemaking procedure unnecessary. A possible underlying reason of the President’s expressed efforts for Congress to act is that it is for Congress to decide whether such authority is provided to the FDA. Nevertheless, both the President and FDA Commissioner Kessler believe the case for FDA jurisdiction over tobacco products is solid because of the mounting evidence which alleges that the tobacco industry previously knew that nicotine was addictive and that the industry may have manipulated the level of nicotine in tobacco products.

99Compare Regulation of Tobacco Products (Part 1), Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 103d Cong., 2d Sess. 73 (1994)(Commissioner Kessler commenting that the FDA would need congressional direction before asserting jurisdiction over tobacco products). with Margaret Ebrahim, Will Washington kick tobacco? Clinton’s war on smoking, NATION, Apr. 25, 1994, at p. 555 (discussing Commissioner Kessler’s correspondence to the Coalition on Smoking OR Health which commented that the growing body of data suggests that tobacco industry intended that many people buy cigarettes to satisfy their nicotine addiction and should the agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis on which to regulate these products under the drug provisions of the Federal Food, Drug and Cosmetic Act).


101See, e.g. President’s News Conference, supra, note 1.; Interview With Tabitha Soren of MTV, 31 WEEKLY COMP. PRES. DOC. 1426 (Aug. 11, 1995); The President’s Radio-Address, 31 WEEKLY COMP. PRES. DOC. 1440 (Aug. 12, 1995); Radio Town Hall Meeting With The President on Larry King (Westwood One Radio Broadcast, Sept. 21, 1995)(transcript available in LEXIS).
If the case for FDA jurisdiction over tobacco products was not politically feasible and to a lesser degree, legally through administrative law, then the proposed rule would have never been introduced by the President. Furthermore, President Clinton is the first president to stand up against the tobacco industry, a political heavyweight.

However, if the introduced legislation in response to the proposed rule is any indication, the movement in Congress seems to be against authorizing jurisdiction over tobacco products to the FDA. The legislation introduced in response to the proposed rule is to specifically prohibit the FDA from regulating tobacco products. The only legislation introduced in the One-Hundred and Fourth Congress to grant any type of authorization to the FDA is the Freedom From Nicotine Addiction Act of 1995. The legislation, however, was introduced in June, 1995 prior to the announcement of the proposed rule.

In addition, the FDA's attempted assertion of jurisdiction is contrary to the intent of Congress because that legislative body has specifically enacted legislation to govern the regulation of tobacco products for children and adolescents. In 1992, by enacting the Synar Amendment, Congress delegated such regulatory authority to the states. The Synar Amendment requires states to enact legislation which prohibits the sale or distribution of tobacco products to individuals under the age of eighteen in order for states to receive federal mental health and substance abuse block grant funds. The states are required

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102The following bills were introduced in response to the FDA's proposed rule: H.R. 2414, 104th Cong., 1st Sess. (1995)(establishing federal authority to regulate tobacco products as a condition to the receipt by State of the Federal health services block grant by requiring stricter state restrictions and declaring that the Secretary of Health and Human Services does not have any authority under the Federal Food, Drug, and Comestic Act); H.R. 2283, 104th Cong., 1st Sess. (1995)(prohibiting the regulation of the sale or use of tobacco products by the Secretary of Health and Human Services under the Federal Food, Drug, and Comestic Act and repealing any regulation issued by the FDA); S. 1262, 104th Cong., 1st Sess. (1995)(establishing certain limitations on tobacco product advertisements and increased enforcement of law relating to underage tobacco use and prohibit the FDA to regulate in any manner tobacco products.); S. 1295, 104th Cong., 1st Sess. (1995) & H.R. 2265 104th Cong., 1st Sess. (1995)(prohibiting the regulation of any tobacco sponsored advertising of any professional motorsports association by the Secretary of Health and Human Services or any other agency of the Federal Government); H.R. 2585, 104th Cong., 1st Sess. (1995)(amending the Internal Revenue Code to increase the excise taxes on smokeless tobacco to an amount equivalent to the tax on cigarettes and to use the revenues for a trust fund for smokeless tobacco use reduction programs).


to enforce these minor restriction laws in a manner "that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18." The Synar Amendment also requires states to use random, unannounced operations to ensure compliance and submit reports on enforcement activities to the Department of Health and Human Services (hereinafter "DHHS"). A state's failure to comply with the Synar Amendment will result in the loss of federal grant money for drug and alcohol abuse. In response to the Synar Amendment, all fifty States now have statutes which prohibit tobacco sales to individuals under the age of eighteen.

On January 19, 1996, the DHHS issued a final rule, "Substance Abuse Prevention and Treatment Block Grants: Sale or Distribution of Tobacco Products to Individuals Under 18 Years of Age," in the Federal Register in order to implement the Synar Amendment. The final rule was issued more than two years after the initial proposed rule was published. The proposed rule of the Synar Amendment issued in 1993 required states to demonstrate that each state was steadily reducing by twenty percent, over a four year period, the success rate of attempted purchases by children and adolescents under the age of eighteen in the random, unannounced inspections. The final rule issued, however, establishes that the Secretary of DHHS will negotiate a strategy with each state for achieving the performance objective over a period of several years. This change eliminated the proposed "one-size-fits-all" standard for the states. The main reason for the change was that not all states have the same ability and enforcement resources.

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108 Id.
111 The notice of the proposed rule was published in the Federal Register on August 26, 1993 at 58 Fed. Reg. 55156.
113 Id.
According to the DHHS, the final rule will complement and be consistent with any rule the FDA may issue. The final rule is directed to the states, while the FDA proposed rule focuses on the tobacco industry and retailers. The DHHS states, the regulatory approaches reflect major differences in the statutory authorities of the respective agencies. The Synar Amendment rule, however, is authorized by Congress while the FDA proposal is without any Congressional approval. This is the major difference in the regulatory approaches.

B. Federalism Principles

Congress' regulatory approach toward tobacco product use restrictions for children and adolescents [Synar Amendment] is consistent with current notions of federalism and the Tenth Amendment. One interpretation of federalism is "that states are entitled to be different - to have different views about the best solutions to their problems and even to have different views about what is a problem and what is not." Additionally, this past year marked a renewed interest in the Tenth Amendment and returning power back to the states. Two main factors can be attributed to the renewed interest, first, general hostility towards the federal government, i.e. 'big government," and second, the idea that problems are best solved by those closest to the problem, state and local governments.

The Synar Amendment and the final rule reflect this governing philosophy and concept. The rule gives States flexibility to devise their own enforcement methods in a manner that can reasonably be expected to reduce the availability of tobacco products to children and adolescent in light of each State's unique circumstances. The Synar Amendment and the final rule are minimum requirements for which the States must adhere to receive federal grant funds. While many tobacco-control advocates have argued that state laws regulating

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114Id.

115Id.

116The Tenth Amendment of the U.S. Constitution provides "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." U.S. CONST. amend. X.


118See United States v. Lopez, 115 S. Ct. 1624 (1995)(striking down a federal statute as beyond the commerce power of the federal government for the first time in sixty years).


121Id. at 1496.
tobacco use by children and adolescents are rarely enforced, the final rule of the Synar Amendment provides incentives, guidance, and assistance for the states to become more involved in a national, comprehensive Congressional program. In short, the guidance provided by the Synar Amendment is the final rule which contains provisions for the states to adhere to in order to receive federal funding; while federal assistance is the funds for enforcement of state tobacco control measures. More specifically, the Synar Amendment requires states to enforce their laws limiting access to tobacco products by children and adolescents and to designate an agency or office to coordinate compliance activities of the Synar Amendment rule. Further, under the Synar Amendment rule, the federal funds provided to the states may be used for state enforcement programs. However, if a state failed to comply with the federal standards, then their funds would be withheld and provided to other states which have complied with the Synar Amendment rule. The final rule also requires states to annually submit to the federal government a report which describe the strategies and activities of the state enforce their laws. The rule also "encourages" states to allow localities to enact stricter laws or more rigorous enforcement of tobacco control measures.

The results of the final rule should be given an opportunity to see how much the rule will reduce tobacco use among children and adolescents before creating additional federal bureaucracies to oversee the states' responsibilities.

On the other hand, the FDA proposed rule is contrary to federalism notions. When many federal agencies are downsized and the era of big government is purportedly over, the proposed rule seeks to expand the scope and mission of the FDA. Without Congressional authority, the FDA is attempting to pursue its own federal policy to place restrictions on tobacco products for children and adolescents. The attempt to assert its jurisdiction comes at a time when the FDA has received much criticism that it cannot handle its already existing regulatory responsibilities such as timely drug testing and approval. According to 1992 figures, only one out of five-thousand drugs complete the regulatory process of laboratory to FDA approval with an approval cycle averaging twelve years. Such statistics prompted a movement toward a total restructure of the


123 President Clinton in his 1996 State of the Union Address proclaimed on three different occasions that the era of big government is over. See Address Before A Joint Session of the Congress on the State of the Union, 32 WKLY COMP. PRES. DOC. 90 (Jan. 3, 1996).

124 Carolyn Lochhead, Deadly Over-Caution, FDA Assailed For Slow Testing Of New Drugs, S.F. CHRON., Oct. 26, 1992 (citing Pharmaceutical Manufacturers Association's study of drug development); see also Lee Bowman, FDA's Drug Export Law Under Congressional Fire, PLAIN DEALER, Aug. 20, 1995, at 4A (discussing a law enacted to enhance U.S. medical exports, but FDA is instead delaying approval by months and years for companies to ship drugs and devices overseas if the drug or device has not already been approved for domestic use); Marlene Cimons, FDA's Generic-Drug Reviews Criticized, L.A. TIMES, Aug. 25, 1989, at 16 (citing a report issued by the inspector general
FDA. Also, criticism has been specifically directed at Commissioner Kessler. Claims are that he is not a team player in that he follows his own agenda with a headline-grabbing style, and that his slow, overly cautious philosophy, with moments of inappropriate regulatory zeal, restricts access to life-saving therapies while increasing medication and health care costs.

If the FDA cannot handle existing responsibilities, then how can the agency tackle the added responsibility of tobacco product regulations in an adequate manner. Moreover, the proposed rule lacks an effective enforcement mechanism. In fact, the FDA admits that the regulations essentially would be self-enforcing.

The states and localities are in a better position to prevent tobacco product use among children and adolescents without federal bureaucratic intervention. Nevertheless, the attorney generals of twenty-seven states wrote to FDA Commissioner Kessler supporting the proposed rule and insisted that a cooperative effort, including federal regulations, was necessary to prevent tobacco use by children and adolescents. The correspondence was the efforts of the National Association of Attorneys General whose membership consists of the fifty states' attorney generals. The twenty-seven attorney generals' supportive correspondence of federal intervention comes at a time when many states are currently suing the tobacco industry to recover payment for Medicaid and Medicare expenses for tobacco-related illnesses. Nevertheless, even without additional federal government assistance, a cooperative effort currently exists under federal and state law through the Synar Amendment. Additional federal intrusion is not necessary until Congress makes that determination.

The determination of whether FDA has any authority to restrict tobacco use must be made by Congress. Congress has delegated such authority to the states and localities. In terms of federalism, the states and local governments should retain regulatory responsibility while improving enforcement of existing tobacco product restriction laws. An aggressive approach by the states and local governments would resolve many of the problems associated with

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125 Peter Stone, *Ganging Up On The FDA*, NAT'L J., Feb. 18, 1995 (discussing a new coalition of industry critics, conservative groups and powerful Republican lawmakers to work for a major restructuring of the FDA).


128 Kent, *Tobacco Control. Coup*, supra note 15 (citing to a FDA spokesperson that if a tobacco agent were to see prohibited material during a retail store visit, the agent would be responsible for its removal).

children and adolescent use of tobacco products without unnecessary federal
government intrusion. The regulating of tobacco use among children and
adolescents is the states' responsibility, not the federal government's.

IV. HOW THE TOBACCO INDUSTRY CONTROLS THE POLITICAL AGENDA FOR
TOBACCO CONTROL INITIATIVES

A. Federal Government

During the announcement of the proposed rule, President Clinton indirectly
conceded that his assault against the tobacco industry on behalf of children and
adolescents may be a political risk for him, especially in the South after he
rejected an enforceable, voluntary agreement. President Clinton had
considered a compromise proposal with the tobacco industry where the
industry would support efforts to fight tobacco use among children and
adolescents in exchange for no regulations. After failing to reach an agreement,
the President subsequently announced the FDA proposed rule. In reality, it is
doubtful President Clinton will suffer any political fallout, even in tobacco
producing states. Instead President Clinton may gain national support
because statistics reveal that the public, including individuals from
tobacco-growing states, supports further restrictions on tobacco use by
children and adolescents. Also, in a public opinion poll conducted after the
announcement, eighty-six percent of adults said yes when asked "should your
Congress member support the FDA proposed rule." Indeed, the FDA
proposed rule may have been drafted to meet the level of tobacco regulation
that the public will support. More than likely, the President's political
advisers (probably more so than his policy advisers) played a significant role in
deciding to go forward with the FDA proposed rule. Therefore, President
Clinton may not risk anything politically, but may gain support for his actions.

The question arises, if the public is supportive of further restrictions on
tobacco products for children and adolescents, then why has not Congress
enacted tougher initiatives or provided the FDA with the authority to regulate
cigarettes. The tobacco industry lobby provides most of the answer.

130 President's News Conference, supra note 1.

131 President Clinton won three of the six largest tobacco producing states: Kentucky,
Tennessee, and by only 5,000 votes Georgia in 1992 Election. See Ron Fournier, President

132 For the level of public support for restrictions on tobacco products for children and
adolescents. See, Marcus, supra note 59 and accompanying text; Bailey, supra note 57 and
accompanying text.

133 News Conference, House Members Hold News Conference To Support The
President's Plan To Regulate Tobacco For Children, Sept. 29, 1995 (transcript available
in LEXIS).
Tobacco is a major agricultural crop in the United States and the tobacco industry accounts for more than 680,000 jobs.\textsuperscript{134} The tobacco industry’s lobbying efforts are conducted by the Tobacco Institute which has controlled potential tobacco restrictions through a sophisticated lobbying scheme.\textsuperscript{135} The tobacco lobby employs a number of former Congressional members as lobbyists.\textsuperscript{136} In addition to former Congressional members, the tobacco industry’s lobbyists include many attorneys who previously were employed in the highest legal positions at the FDA.\textsuperscript{137} According to a 1993 report, the tobacco lobby has ensured that members of Congress rarely have to actually vote against tobacco control legislation because the industry "quietly kills" such initiatives in various committees without much media attention.\textsuperscript{138}

The tobacco industry’s real source of strength is political campaign contributions. For example, according to a 1995 Common Cause study, from 1989 to 1994, seventy-three percent of senators accepted campaign contributions from the tobacco industry and sixty-six percent of House members accepted tobacco industry’s campaign contributions in the 1994 election.\textsuperscript{139} The tobacco industry has contributed more than 16.6 million dollars to federal candidates, political action committees, and political party committees since 1985.\textsuperscript{140} During the period of 1993 to 1995, the tobacco industry gave almost $2 million in "soft money"\textsuperscript{141} contributions to Republican

\textsuperscript{134}Hank Cox, Feds and Smokers Fume Over the Right to Inhale, WASH. TIMES, Apr. 24, 1995, at 14 (citing to a 1992 Price Waterhouse Study).


\textsuperscript{136}Vicki Kemper, The Inhalers; They May Not Smoke Tobacco Products, But Some In Congress Are Addicted to the Industry’s Money, COMMON CAUSE MAG., Jan./ Feb./ Mar. 1995.

\textsuperscript{137}The former FDA attorneys employed with the tobacco industry include: Richard Merrill, former chief counsel the during Carter Administration; Richard Cooper, former chief counsel; Thomas Scarlett, former chief counsel during the Reagan Administration; Arthur Levine, former deputy general counsel of litigation from 1978-91; and Donald Beers, former associate chief counsel for enforcement from 1978-85. See Milo Geyelin, Tobacco Industry Gets Help From Ex- FDA Lawyers, WALL ST. J., Jan. 16, 1995 .


\textsuperscript{139}Kemper, supra note 136.

\textsuperscript{140}Id.

\textsuperscript{141}"Soft money" describes campaign contributions raised from sources that, if given directly to candidates, are illegal in federal elections. The campaign contributions are channeled to state political party organizations, and spent by the state parties on election activities. The soft money exception is a loophole which political parties have used to their full advantage. See Clarisa Long, Note, Shouting Down the Voice of the People: Political Parties, Powerful PACs, and Concerns About Corruption, 46 STAN. L. REV. 1161, 1167 (May, 1994).
party committees. Further, since 1985, the eleven tobacco political action committees have contributed more than 10.6 million dollars to federal candidates and political action committees.

More recently, the tobacco industry increased their contributions to Republicans last year which reflects a new, more partisan effort as the industry lobbies against the Clinton Administration and the FDA proposed rule. In fact, tobacco industry "soft money" contributions were nearly 2.3 million dollars in 1995. Philip Morris and RJR Nabisco Holdings Corp. contributed 1.7 million dollars to Republicans which is nearly twice the amount contributed to Republicans in 1994. On the other side of the political fence, Democrats, who previously received support from the tobacco industry, have received a much smaller amount. For example, the RJR Nabisco political action committee's overall contribution in 1995 was a twenty-seven percent increase from the previous year; yet the amount contributed to Democrats in 1995 was half the amount received the Democrats received in 1994.

In addition to political action committees, tobacco executives make large political contributions out of their own pockets. Since 1989, fifteen executives have contributed 162,700 dollars to federal candidates, leadership political action committees and party committees and 169,840 dollars to tobacco industry political action committees.

According to the Common Cause study, Congress ignores the public health aspects of tobacco use and public opinion polls because it is the tobacco industry rather than the public that rewards or punishes Congress for their votes on tobacco control initiatives. The political cost of challenging tobacco interests is the loss of an easy source of campaign contributions and an increase to a challenger. A study in the Journal of American Medical Association found that nothing influences tobacco legislation votes by Congress more than tobacco industry campaign funds. The study determined that House members receiving the most tobacco contributions were fourteen times as likely to vote with the tobacco industry as opposed to a member receiving less contributions, and Senate members who received the most contributions were

142 Kemper, supra note 136.
143 Id.
144 David Rogers, Tobacco Companies Boost Contributions To the GOP, While Democrats Get Less, WALL ST. J., Feb. 12, 1996, at B6.
145 Id.
146 Id.
147 Rogers, supra note 144, at B6.
148 Kemper, supra note 136.
forty-two times more likely to vote with the tobacco industry.\textsuperscript{150} This study demonstrated a consistent and strong relationship between the amount of tobacco contributions received and a Congress member’s position on tobacco control legislation. The more contributions received, the less likely the Congressperson would support tobacco control measures. Additionally, Republicans and Congress members representing tobacco producing states were also less likely to support such legislation. The strength and consistency of belonging to the Republican Party and representing a tobacco producing state, though, still did not have the impact as the amount of tobacco contributions received.\textsuperscript{151} According a Journal of American Medical Association Editorial, the study "reveals a high correlation between campaign donations and the failure of legislators enact tobacco control measures." The editorial also claimed that the study exposed how tobacco contributions corrupt the legislative process and that the study should be utilized for efforts to enact campaign finance reform. The tobacco industry in response to the study found "striking ironies" in that the American Medical Association’s Political Action Committee outspent tobacco interests by almost two to one.\textsuperscript{152}

B. State Governments

Besides wielding heavy influence in Congress, the tobacco industry lobby is also prevalent in state legislatures. A second study published in the same issue of the Journal of American Medical Association found that the tobacco industry’s state campaign contributions have also produced results favorable to the tobacco industry. Once again, legislative behavior followed tobacco contributions rather than constituent support.\textsuperscript{153} From January 1, 1991 to December 31, 1992, the tobacco industry contributed an average of 10,402 dollars per member of the California General Assembly. Seventy-four of the eighty state legislators accepted the contributions, and the Assembly speaker received 221,367 dollars in contributions.\textsuperscript{154} Subsequent to the 1994 published study, the state of California in 1995 became the first state in the nation to attain the highest grade, "outstanding," on the Coalition on Smoking OR Health’s second annual Report Card for State Tobacco Control.\textsuperscript{155} The report card assessed the tobacco control performance of state governments.\textsuperscript{156} The 1995
grade was awarded after the state of California enacted smoke free workplace and minor access laws and defeated a referendum supported by Philip Morris to impose weaker statewide smoking regulations. Nevertheless, the tobacco industry in California employs influential lobbyists and public relation firms and contributed 738,166 dollars to legislative candidates in 1994.157

Inside the state capitol, the tobacco industry's strategy of lobbying has been dubbed "astroturf" because the industry presents well-orchestrated opposition to tobacco control initiatives as an ordinary "grassroots" movement.158 The tobacco industry realizes that the industry is widely disliked by the public. The tobacco lobby, therefore, often shuns publicity and prefers to work behind the scenes with organizations in the business community.159 The tobacco industry has been repeatedly referred to as the "invisible enemy" by tobacco control advocates.160 The tobacco industry utilizes small business owners, hospitality industry associations, and other groups funded by the tobacco industry to testify at committee hearings or sponsor letter writing campaigns against tobacco control initiatives.161

The tobacco industry’s primary legislative goal at the state level is to preempt local government's discretion to enact tobacco control ordinances. The legislation is usually promoted as a pro-health initiative that establishes uniform restrictions, which are usually weak, and local governments are then prevented from adopting more restrictive initiatives.162 State preemption clauses are a "Holy Grail" for the tobacco industry because local communities have taken the lead in protecting children and adolescents from access to tobacco products.163 By eliminating local control, the tobacco industry removes one of the most effective tools to reduce tobacco use among children and adolescents. The tobacco industry claims that preemption is necessary in order to implement statewide standards for the sale, promotion, and display of tobacco products.164 This is to avoid a patchwork of different local laws. Since July, 1992, thirty States enacted additional legislation to prevent children and

"Poor: AZ, ID, IN, KS, MA, MO, MT, NJ, ND, NM, OH; And "Failing:" AL, DE, GA, KY, LA, MS, NC, OK, PA, SC, SD, TN, TX, VA. Id.

158Id.
159Id.


161Id. at 799.


163Russ Freyman, Butting In, GOVERNING, Nov., 1995, at 55.

adolescent access to tobacco products, however, ten of the thirty new statutes preempted more stringent ordinances at the local level.\textsuperscript{165} Also, sixty-three percent of all children and adolescent tobacco-control statutes that contain preemption clauses have been enacted since July, 1992.\textsuperscript{166} In 1995, preemption legislation came up for debate in twenty-eight states.\textsuperscript{167} The tobacco industry tactic is to show greater willingness to accept some restrictions on tobacco use and sale, while aggressively seeking preemption provisions in the legislation.\textsuperscript{168} Because the tobacco lobby enjoys great influence, the tobacco industry has quietly championed weak legislation in state legislatures to undermine strong local ordinances aimed at the reduction of tobacco sales to children and adolescents.\textsuperscript{169}

The tobacco industry argument regarding statewide uniformity of tobacco regulations is extremely weak. Similarly, the National Rifle Association argues the same point when fighting local gun control ordinances by cities which are more restrictive than state gun control laws. The tobacco industry's argument, however, is flawed because it is at the local level where regulations have been most successful in keeping tobacco products out of the hands of children and adolescents. The preemption of local ordinances directly removes the homerule powers of local governments and their ability to adequately address specific areas of public policy such as tobacco control. Furthermore, local ordinances are not unduly burdensome on retailers and do not restrict adults' right to purchase tobacco products. In fact, according to an Indianapolis Star newspaper article, "with over 900 local ordinances on the books in this country, not one business has gone under as a result of a local tobacco prevention ordinance." The homerule powers of localities provide for a local solution to a problem which may differ among the localities of a particular state. If the tobacco industry lobby was serious about preventing tobacco use among children and adolescents, then the industry would not support weaker state measures which preempt local measure which have been proven successful. Instead, the tobacco industry would support strict statewide measures. The tobacco industry logical is fatally flawed based on their reasoning for statewide uniformity.

V. A STATE AND LOCAL POLICY TO SUBSTANTIALLY REDUCE TOBACCO USE AMONG CHILDREN AND ADOLESCENTS

The tobacco industry publicly agrees that children and adolescents should not use tobacco products. The tobacco industry has even attempted voluntary initiatives to prevent children and adolescents' access to tobacco products. For

\begin{footnotesize}
\begin{enumerate}
\item State Laws, supra 34, at 24.
\item Id.
\item Freyman, supra note 163.
\item Id. at 56.
\item Andrew Wolfson, Tobacco On Trial, LOUISVILLE COURIER J., Nov. 13, 1994, at 15A.
\end{enumerate}
\end{footnotesize}
example, Phillip Morris began a program called "Action Against Access" and RJ Reynolds provides parents with "How You Can Help Discourage Kids From Smoking" kits, schools with "Right Decisions, Right Now" program materials, and retailers with "Support the Law. It Works." campaign materials. The tobacco industry also claims to support the final rule of the Synar Amendment and believes that the states are best equipped to determine how children and adolescent access laws should be implemented and enforced.

The tobacco industry, however, has been able to prevent the enactment of meaningful legislation in many states to reduce tobacco use among children and adolescents and has weakened local tobacco control through preemption. The preemption of local ordinances is the deathknell in the fight to reduce tobacco use among children and adolescents. This is so because action by local governments has proven to be most effective in enforcing and enacting laws to prevent tobacco use among children and adolescents.

At the local level, it is difficult and expensive for the tobacco industry to lobby against every proposed tobacco-control ordinance. In fact, tobacco-control advocates, who are usually local health community leaders, have greater political influence at the local level to direct policy than the tobacco industry.

According to a Public Health Report, a local ordinance which has a local license provision and penalty violations of suspension or revocation of the license for selling tobacco products to minors is an effective tool to reduce tobacco use among children and adolescents. After enacting such an ordinance in 1989, the City of Everett, Washington experienced an overall decline in tobacco use among tenth grade students of nearly six percent, but more important, the city experienced a thirty percent increase by retailers requesting proof of age when children and adolescents attempted to purchase tobacco products.

In a widely cited example of local governmental success published in Journal of the American Medical Association, the City of Woodridge, Illinois, population of 25,200, enacted legislation modeled after the city's liquor control ordinances treating tobacco products and alcohol alike. The ordinance enacted in 1989 contained fifty dollar licensing fees for tobacco vendors, enforcement...

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171Philip Morris U.S.A.'s Statement in Response to HHS rules Implementing Congress' Decision to Have States Curb Tobacco Sales to Minors, BUS. WIRE, Jan. 18, 1996.


173Jacobson, supra note 160, at 814.


175Id.
by local police, and a twenty-five dollar penalty for minor possession. In the year and one half after the ordinance's enactment, a survey of seventh- and eighth-grade students who reported experimenting with cigarettes decreased from forty-six percent to twenty-three percent and the proportion of daily underage cigarette smokers decreased from sixteen percent to five percent. Moreover, in that same period, through the use of "sting" compliance checks, the City found that the proportion of retail stores selling cigarettes to minors substantially decreased from seventy percent to three percent. According to the Journal of the American Medical Association, the success of the City of Woodridge was due to police conducted compliance checks, extensive community education, and media exposure. Today, the ordinance remains highly successful after six years of its enactment by the Woodridge City Council. This author contacted the City of Woodridge Police Department and interviewed Woodridge City Police Sergeant Ed Kelter who is in charge of the ordinance's enforcement mechanism. According to Sergeant Kelter, the statistics regarding illegal sales from the journal article have "remained the same with some variables." The City continues to conducts four random sting operations each year or if a report is received, the police will conduct a compliance check on that specific retailer. Sergeant Kelter also commented that the ordinance also caused a number of businesses which included national franchise restaurants to remove vending machines and discontinue selling tobacco products because "its not worth the trouble." The Woodridge Police sergeant attributed the continued enforcement of the ordinance as the main reason for the continued reduction of tobacco use among children and adolescents.

The City of Chicago also has been successful in reducing tobacco sales to children and adolescents by local ordinances. In Chicago, store owners violating illegal sale laws to minors are fined $200 and can lose their licenses to sell tobacco products. Through the use of "sting" operations conducted by the Chicago Department of Revenue every two months, the rate of illegal sales decreased from eighty-seven percent to sixteen percent.

A licensing ordinance with penalties for sales to children and adolescents has been proven effective elsewhere. For example, the City of Indianapolis in 1994 enacted a licensure ordinance requiring fifty dollars annual fees and includes a five hundred dollar fine for a first offense and one thousand dollar fine for a second offense for the sale tobacco products to minors. A survey of

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177Id.

178Id.

179Id. at 3161.

random "sting" compliance checks conducted by Doctors and Lawyers for a Drug-Free Youth revealed that not one store sold tobacco products to the survey's underage volunteers.\textsuperscript{181}

Another effective local tool is education. Education combined with enforcement has had a significant effect on retail store tobacco sales to minors.\textsuperscript{182} A study published in the Journal of the American Medical Association was conducted to examine the effects of community education and enforcement of access tobacco laws in four Northern California communities. It was found that after implementation of community and retail merchant education and enforcement activities the rate of illegal tobacco sales decreased from seventy-one percent to twenty-four percent in a two year span.\textsuperscript{183}

There has been a recent change in the nation's cultural attitude towards tobacco use among children and adolescent. For instance, fifteen years ago widespread support for tobacco restrictions would have been virtually nonexistent. A major turning point for government involvement came when former Surgeon General Everett Koop suggested in the Surgeon General's 1988 report on nicotine addiction that tobacco sales should be controlled at least as tightly as the sale of alcoholic beverages.\textsuperscript{184}

Tobacco should be treated like alcohol, a serious, adult product with serious consequences for minors caught with tobacco products. The perception of tobacco products has changed. Unfortunately, many Congress members and state legislators have not caught on to the cultural change, and instead have responded to the tobacco industry's dollars. As public awareness increases about the problem of tobacco use among children and adolescents and continued negative publicity follows the tobacco industry, dramatic legislative changes will occur. In fact, a major breakthrough recently occurred when Liggett Group became the first tobacco company in history to settle a health-related lawsuit and agreed to donate a portion of its profits over the next twenty-five years for programs to encourage tobacco users to quit.\textsuperscript{185} In addition, the company also voluntarily agreed to begin complying with certain provisions of the FDA rule. Liggett, which only represents two percent of the tobacco market, asserted that the company was not conceding that the FDA has a right to regulate tobacco products. While the aftermath of the Liggett settlement has not taken full effect, it appears the tobacco industry may have

\footnotesize{\textsuperscript{181}Edwin Brown, \textit{Local laws can put the bite on merchants selling cigarettes to minors}, MED. UPDATE, Sept., 1995, at 1.  

\textsuperscript{182}Ellen Feighery, et al., \textit{The Effects of Combining Education and Enforcement to Reduce Tobacco Sales to Minors}, 266 JAMA 3168 (Dec. 11, 1991).  

\textsuperscript{183}Id. at 3170.  


\textsuperscript{185}Henry Weinstein, \textit{Tobacco Firm Agrees To Settle a Health Suit}, L.A. TIMES, Mar. 14, 1996 at 1.}
finally cracked because previously the tobacco companies were under the code of "one for all and all for one". The result of this agreement should bring about the enactment of stricter regulatory measures at the state and local level.

Nevertheless, a well-organized counterattack to the tobacco industry must be mounted by parents, teachers, educational groups, medical societies, public health associations, anti-tobacco organizations, and municipalities at the state and local level. There is power in numbers and accordingly federal, state and local elected officials, will eventually respond to such grassroots efforts. Such efforts need to be directed at the state and local level of governments unless Congress grants authority to the FDA to regulate tobacco products. This congressional action, however, is extremely doubtful.

Therefore, in order to effectively combat tobacco use among children and adolescents comprehensive legislation should be enacted at the state or local level. This is where Congress delegated such authority. The legislation should include the banning of vending machines; a retail licensing system similar to alcohol sales; civil penalties for minors found in possession of tobacco products; civil fines for retail stores and license suspension or revocation; enforcement by local police and health departments through the use of random "sting" operations; and community-based educational programs. The license fees would provide a source of revenue and self-funded enforcement. It is this type of legislation which has substantially reduced tobacco use among children and adolescents. The enforcement component is the key to success in the reduction of tobacco use among children and adolescents.

The main reason for banning vending machines is such machines provide easy access for children and adolescents to purchase tobacco products. As noted earlier in this note, nine studies which examined illegal vending machine sales found that children and adolescents were able to purchase tobacco products on average eighty-eight percent of the time. By eliminating vending machine sales, children and adolescents will have less access to tobacco products. By reducing access to tobacco products, the percentage of children and adolescents using such products will decrease. The City of Woodridge is a prime example on the effect of aggressive enforcement.

Furthermore, a retail licensing system also has been successful in reducing tobacco product use as noted earlier. A retail licensure scheme has many benefits. First, the license fees received by the state or locality may be used to enforce laws prohibiting sales to children and adolescents through the use of police or local health agents whom would enforce the regulations. Secondly, the fees also could be used for an enforcement fund. The funds could be used in a variety of areas to reduce tobacco use among children and adolescents. For example, random sting operations on various retailers to ensure compliance could be financed through the fund. Additionally, if a retailer conducts an illegal sale, then a fine could be assessed which also would be placed in the fund. The funds could be used by local schools for educational programs to warn children and adolescents on the dangers of using tobacco products. Many schools already have similar drug and alcohol programs. Besides teaching about the dangers, the educational programs would also inform children and adolescents about the law. The educational programs should inform children and adolescents that tobacco products are not like soft drinks, candy bars, and
chewing gum, but rather tobacco products are extremely harmful products to their health.

Moreover, a licensing system would provide such a listing of all retailers selling tobacco products. Therefore, the retail licensing system could be used by the locality to focus their efforts to where illegal sales to children and adolescents are most prevalent.

Additionally, a key component to reduce tobacco use among children and adolescents is the threat of revoking the licenses of retailers who violate the law. This aspect perhaps is more compelling than a fine. If retailers deny selling tobacco directly to children, the point of purchase is severed, thus, making it more difficult for children and adolescents from acquiring access to tobacco products. In order to determine if illegal sales are being conducted, a state or locality should perform random sting operations using undercover children and adolescents on a regular basis. This approach would have the effect of making retailers hesitant to make an illegal sale to children or adolescents.

Moreover, children and adolescents caught illegally possessing or using tobacco products should not go unpunished. Civil monetary penalties should be imposed as well as community service for such children and adolescents.

The strong enforcement of regulations prohibiting children and adolescents from purchasing tobacco products will resolve a number of the problems of tobacco use among children and adolescents. This effort will send a message to children and adolescents that tobacco products are an adult product.

On the other hand, placing restrictions on the labeling and advertising of tobacco products will not have such an immediate impact as strict sales restrictions. Despite the fact that many studies conclude that the tobacco industry markets their products towards children and adolescents, the more compelling reason for children and adolescents to begin tobacco product use is more than likely peer pressure. Most children and adolescents will use tobacco products with another friend. It is not because the child was influenced by a "Joe Camel" advertisement. While not advocating that tobacco industry marketing techniques do not have any effect on tobacco use of children and adolescents, advertising restrictions are not nearly effective as strict sales restrictions which should be imposed by the states and localities to reduce the thousands of children and adolescents who become regular users of tobacco products each day. Instead, the problem should be focused at the point of purchase and at the children and adolescents attempting to purchase or use tobacco products.

VI. CONCLUSION

Although the FDA has a compelling argument from a public health point of view, the FDA proposed rule to unilaterally assert jurisdiction over tobacco products is beyond the agency's statutory authority and contrary to the intention of Congress. Despite public opinion displaying extensive support for such action, the proposed rule is beyond the FDA's jurisdiction until Congress provides such authority. Instead, Congress through the Synar Amendment delegated such authority to the states. The FDA proposed rule, unfortunately, would not adequately control tobacco use among children and adolescent because the proposed rule lacks the necessary local enforcement tools which
have been successful in keeping tobacco products out of the hands of children and adolescents.

The more appropriate solution to reduce tobacco use among children and adolescents is for states and local governments to enact tobacco control initiatives similar to laws regulating alcoholic beverage sales. Like alcohol, tobacco products are a serious, adult product, and tobacco control initiatives should have serious consequences when retailers sell tobacco products to children and adolescents and when children and adolescents are caught with such products.

Additionally, local governments should have the ability to enact tobacco control initiatives more restrictive than state laws. Local ordinances have proven to be effective. Preemption of local tobacco control initiatives is the deathknell of reducing tobacco use among children and adolescents. This means coordinated efforts must be conducted to fight preemption clauses at the state level.

By preventing the corner neighborhood store from selling tobacco products to "little Johnny or Jane," a major aspect of the problem of tobacco use among children and adolescents will be resolved. The state and local levels of government are best capable of preventing tobacco use among children and adolescents, not the federal government.

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