

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

YOUTH USE OF CIGARS

Federal, State Regulation and Enforcement



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**FEBRUARY 1999
OEI-06-98-00020**

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EXECUTIVE SUMMARY

PURPOSE

To describe the regulatory environment of cigars at the national and State levels, as well as Federal and State tobacco control and enforcement activities regarding minors' access to and use of cigars.

BACKGROUND

New evidence of widespread minors' use, coupled with new scientific evidence about the health risks of cigar smoking (such as cancers of the lungs, larynx, oral cavity, and esophagus), is causing growing concern about the extent of minors' use of cigars and also about the adequacy of attempts to regulate access to them. The President and Secretary of Health and Human Services have initiated efforts to reduce minors' tobacco use. This effort has involved a number of agencies, such as the Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration. This study supports their efforts. It involved reviews of existing Federal regulatory authority and agency oversight responsibilities for cigars, along with systematic collection of information from all 50 States and the District of Columbia.

FINDINGS

Cigars have not faced the same degree of Federal regulation and oversight as other tobacco products, such as cigarettes and spit tobacco.

Cigars do not include a U.S. Surgeon General's warning label, no Federal laws require cigar manufacturers to report their ingredients and, aside from little cigars, they face no advertising restrictions on television and radio. Additionally, cigars are not included in the Food and Drug Administration's (FDA) newest tobacco regulations. Through these regulations, the FDA asserted jurisdiction to regulate cigarettes and spit tobacco as nicotine-delivery devices under the Federal Food, Drug and Cosmetic Act. The only Federal enforcement oversight for cigars is through the Synar Amendment, which is administered by the Substance Abuse and Mental Health Services Administration and was added to the Public Health Service Act to strengthen efforts to reduce the sale of all tobacco products to youth. However, cigars are only implicitly addressed. Under Synar, the only explicit Federal requirement for States to comply with is to conduct yearly, random, unannounced inspections of vendors to measure tobacco sales to minors. In working with the States to develop an appropriate methodology for implementing the Synar Amendment, SAMHSA weighed variables such as the relative volume of cigarette versus cigar usage by minors and resource constraints faced by States. Based on State resource constraints and higher use of cigarettes than cigars and other tobacco products by minors, SAMHSA determined that the most effective way to reduce the sale of tobacco products to youth was to prioritize State inspection activity on cigarettes only.

State enforcement of laws and regulations prohibiting the sale to, and use of cigars by, minors is currently severely limited.

All States and the District of Columbia (51) have tobacco laws broad enough to encompass cigars, with most explicitly stating that cigar sales to minors and their purchase, possession, or use of cigars are prohibited. However, States do not evenly enforce these laws and regulations governing minors' access to tobacco. Cigars, in particular, currently receive a very low enforcement priority. While 44 States reported a variety of options for controlling minors' access to cigars, such as follow-up on complaints (29), compliance checks using minors (27), and observation of minors' attempted purchases (16), most of these methods are rarely or seldom applied. Additionally, many States lack a general awareness of the extent of cigar sales to minors, the ease with which minors can purchase cigars, and the degree to which minors' use of cigars is a problem in their State.

Lack of resources and a low enforcement priority are seen as the most significant barriers to effective control of cigar use by minors.

The biggest barrier, listed by 31 State contacts, dealt with insufficient resources for enforcement and/or a general unwillingness by the community and local law enforcement authorities to prioritize cigar enforcement. Secondary to issues of priority and resource constraints, 13 State contacts listed a lack of awareness of the dangers of cigar usage and the extent of minors' usage in their State as a major barrier. Twelve State contacts reported problems with retailers, such as failing to enforce the laws, placement of cigars in accessible locations, and the lack of licensing. Five State contacts listed the barrier of industry marketing practices linking cigars with glamour and success, as well as product placement in youth-oriented movies and TV shows. Four State contacts mentioned the barrier created by the omission of cigars from the FDA regulations.

RECOMMENDATIONS

We found the shield of protection in place for other tobacco products is largely missing for cigars. The information collected through our background research and this study highlights the need for a concerted DHHS strategy to address the emerging health risks of cigar usage.

We recommend that the Department, under the leadership of the Assistant Secretary for Health develop an action plan to address the public health risks posed by cigars, particularly access by youth. As a first step, we recommend an initiative to inform the public through a public awareness and educational effort appropriate for cigars. This effort could also include pursuing a collaborative effort with the Federal Trade Commission and Congress to initiate a Surgeon General's Warning Label for cigars. As a second step, the Department should address the need for additional research on cigars including patterns and prevalence of use, youth access and ease of purchase, health effects, addictive potential, use of cigars to smoke marijuana, and an assessment of the adequacy of the Department's data collection and survey capacity for monitoring cigar use trends.

Data gleaned from this research may provide information that will enable the Department to address more specific issues such as how best to expand enforcement efforts under the Synar Amendment to address cigars, including identifying resources needed to accomplish this, and whether FDA should initiate the investigatory process for asserting jurisdiction over cigars comparable to that exercised by the FDA over cigarettes and spit tobacco and/or have Congress expressly affirm FDA's authority to regulate cigars.

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INTRODUCTION

PURPOSE

To describe the regulatory environment of cigars at the national and State levels, as well as Federal and State tobacco control and enforcement activities regarding minors' access to and use of cigars.

BACKGROUND

This report describes existing Federal and State laws, regulations, and enforcement mechanisms in place to address minors' use of cigars. Currently, ample information is available regarding minors' access to cigarettes and the corresponding mechanisms used to control cigarette usage. However, far less is known about the regulatory environment and enforcement mechanisms for cigars and spit tobacco (snuff and chewing tobacco). This report focuses on information about cigars.

The impetus for this OIG study is multi-faceted. First, this study contributes to efforts by the President and Secretary of Health and Human Services (HHS) to reduce minors' tobacco use. Second, it addresses information requested by the Centers for Disease Control and Prevention, Office on Smoking and Health, by exploring the issues surrounding cigar use by minors and States' efforts in reacting to this emerging problem. Third, it contributes to recent efforts made by the National Institutes of Health through the National Cancer Institute and the Federal Trade Commission to better understand the scientific and regulatory environment for cigars, as opposed to cigarettes.

Evidence of Cigar Use Among Minors

In May 1997, the Centers for Disease Control (CDC) first published data showing 26.7 percent of U.S. male and female teenagers 14 to 19 years of age and 24.4 percent of those 14 to 16 years of age had smoked at least one cigar in the last year.¹ These numbers were even more striking for males, with 37 percent in this national random survey having smoked a cigar in the last year. Similar evidence was found in two separate State surveys of youth. A Massachusetts study found that 28.1 percent of 9th to 12th grade students had smoked a cigar in the past year and 14.5 percent had smoked at least one cigar in the past month.² Cigar use among males in grades 8 through 12 was also significantly higher than spit tobacco use.³ A recent California tobacco survey found that approximately 34 percent of males and 17 percent of females ages 16 to 17 and 8 percent of males ages 12 to 13 had smoked at least one cigar in 1996.⁴

More alarming is the percentage of high school students nationally that have used cigars in the past month. Twenty-two percent of both male and female high school students combined were current cigar users (used in the previous 30 days), according to CDC's 1997 Youth Risk Behavior Survey.⁵ Specifically, 31.2 percent of male students had used a cigar in the past month and 10.8 percent of female students.⁶ The percentage of current cigar users far surpasses the percentage of spit tobacco users for high school males and females (22 and 9.3 percent), although

the attention cigars have received nationally and at the State level has been far less. As a counterpoint to these national and regional data, are the results of SAMHSA's 1997 National Household Survey on Drug Abuse which shows current past month cigar use by 12-17 year olds to be only five percent.⁷

There is also evidence to suggest that minors may be obtaining cigars with the same or greater ease than cigarettes. A study of ninth grade students in two New York counties found cigars are more easily obtained by minors than cigarettes.⁸ This combination of teen use of cigars and relative ease of purchase by minors has caught public health officials off guard.

Health Effects of Smoking Cigars

Until recently, very little was known about the health risks of cigar smoking by the scientific and public health community. In fact, less than one percent (37 of 3,994) of cigar-related stories in 26 major U.S. newspapers from 1994 to early May 1997 dealt with the health risks of cigar smoking.⁹ Although an earlier Surgeon General's report warned of some of the risks of cigar smoking, cigars were more commonly assumed to be a much safer product than cigarettes because cigar smoking does not require inhalation to obtain the effects of nicotine.¹⁰

The National Cancer Institute's (NCI) recently released monograph entitled, *Cigars: Health Effects and Trends*, is the first comprehensive work scientifically documenting the health risks of smoking cigars.¹¹ Some European studies have observed an increased risk of stroke among cigar smokers.¹² This monograph presents evidence showing causal relationships between regular cigar use and cancers of the lungs, larynx, oral cavity, and esophagus.¹³ People who smoke cigars almost triple their chances of developing lung cancer and are up to 10 times more likely to die from mouth or throat cancer than nonsmokers.¹⁴

Another study by the Kaiser Permanente Medical Care Program followed 225 men who smoked an average of two cigars a day for 10 years. These men were found to have a 25 percent higher risk of death during a 13 year follow-up, compared to 14,200 men who never smoked any tobacco products.¹⁵ This study also showed regular cigar smokers had an increased risk of some forms of heart disease. This new information, coupled with recent studies showing rising cigar use among minors, has heightened concerns about the extent of minors' use of cigars and also about the adequacy of attempts to regulate minors' access to cigars.

Images of the New Cigar Smokers

The stereotypical cigar user, formerly mostly older adult men, now includes much younger users. Strategic product placement of cigars, the practice of paying Hollywood brokers to place cigars in the mouths of popular actors and young-looking adults in movies or television sitcoms, has enforced the new image of today's younger cigar users and increased the social acceptability of cigar smoking.¹⁶ Responding to attacks from anti-tobacco organizations and some lawmakers, the Cigar Association of America recently announced it will no longer support the practice of product placement.¹⁷ The Association plans to "admonish" its members to halt the practice.¹⁸

Additionally, cigars smoked today are available in a greater variety of flavors, sizes, and price ranges that appeal to a wider audience. While there have been sharp increases in sales of premium cigars, manufacturers of lower-end cigars have also realized substantial profits.^{19,20} These low-end cigars are available in grocery or convenience stores and can be purchased for as little as 50 cents or less. Clearly, these low-end products are not the same as those highlighted in new cigar magazines, such as *Cigar Aficionado*. However, the messages of glamour and success that are associated with premium cigar smoking appear to be influencing users of all types of cigar products and all ages.²¹

Types of Cigars

Although cigars differ vastly in size and price, for taxation purposes the government uses two classification levels: small and large cigars.²² Small cigars, referred to as “little” cigars, are similar to cigarettes in size (70-120 mm in length) and packaging (20 per pack).²³ For tax purposes, small cigars are required to weigh less than 3 pounds per 1,000 cigars. The tax category for large cigars includes all cigars that weigh more than 3 pounds per 1,000 cigars. However, great variation exists as to the size of the cigars within the tax classification of large cigars. These cigars come in a variety of sizes ranging from 12.7 to 21.4 cm in length and 12 to 23 mm in diameter. To help differentiate this large variation, the cigar industry has developed its own definitions of cigars in the large cigar tax classification. One of the primary distinctions the industry makes is between manufactured cigars and hand-rolled, also known as premium, cigars.

Manufactured Cigars

Price also helps differentiate manufactured cigars from premium cigars. Manufactured cigars are often sold in packs of five and cost less than \$2.00. The low cost of producing these cigars is attributed to the fact that they are machine-made and use reconstituted cigar tobacco for the binder and/or wrapper. However, there are many variations of manufactured cigars. A few of the more common types of manufactured cigars are described below.

▶ *Cigarillos and Pipe Tobacco Cigars*

Cigarillos and pipe tobacco cigars, two popular types of manufactured cigars, often have a plastic or wood tip and a milder taste. Many cigars in this grouping also come in flavors, such as cherry. In many States, users can purchase these cigars in packs of five for less than \$2.00 or as singles for 50 cents at local convenience or grocery stores. It is currently unclear what type of consumers are using this product. However, evidence from the companion OIG study, “Youth Use of Cigars: Patterns of Use and Perceptions of Risk”(OEI-06-98-00030), indicates that minors often use cigarillos and pipe tobacco cigars because they are easy to purchase, are milder in taste, and cost less.

▶ *Regular Sized Cigars*

A third type of manufactured cigars is the regular sized cigars. For taxation purposes, these cigars are taxed as large cigars, but they are actually smaller than many of the premium cigars.

These cigars are also distinguished by their price and mass production, usually selling for less than \$2.00 for a pack of five cigars. Many cigar manufacturers also sell a type of cigar with a blunt cut tip. Although these cigars are sold by the manufacturer with tobacco in them, evidence from the companion OIG study, “Youth Use of Cigars: Patterns of Use and Perceptions of Risk” (OEI-06-98-00030), shows teens often replace the tobacco with marijuana, a popular practice called “blunting.” Teens report using cigars to smoke marijuana because cigars burn more slowly, they obtain a better high, and can easily buy them at grocery stores and convenience stores. It is currently unclear how many of the teens smoking cigars are using the cheaper cigars for smoking marijuana and how many are smoking them as they are intended to be smoked. What we do know is that several large manufacturers recently added new blunt cigars to their product lines.²⁴ We also know that the use of cigars for smoking marijuana is openly promoted by the songs of several hip-hop music artists.²⁵

Premium Cigars

Comparatively, premium cigars are usually hand-rolled, cost over \$1.00 per cigar, and are often imported. Premium cigars include more extensively fermented tobacco and are more expensive, usually ranging in price from \$1.00 - \$20.00 a cigar. Although premium cigars are currently sold in some convenience stores, they are more commonly found in specialty tobacco shops. Premium cigars are marketed in magazines such as *Cigar Aficionado* and *Smoke*. Early evidence from the companion OIG study, “Youth Use of Cigars: Patterns of Use and Perceptions of Risk” (OEI-06-98-00030), shows that, due to their higher price, minors are not commonly smoking premium cigars.

Secretary’s Initiative to Reduce Tobacco Use Among Teens and Preteens

In 1996, the President set a goal of reducing tobacco use among young people by 50 percent in seven years. To coordinate the Department’s efforts to achieve this Presidential goal, the Secretary established the Interagency Initiative to Reduce Tobacco Use Among Teens and Preteens, with the Centers for Disease Control and Prevention (CDC) as the lead agency. Participating agencies include the Administration for Children and Families (ACF), Food and Drug Administration (FDA), Indian Health Service (IHS), Health Care Financing Administration (HCFA), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA), components of the Office of the Secretary of HHS, and non-HHS agencies such as the Department of Education and Department of Justice. Through collaborative efforts, the Initiative attempts to take advantage of established linkages among local, State and Federal agencies, community organizations, businesses, and the entertainment industry. It also seeks to create a national infrastructure for tobacco control activities and to increase the outreach capabilities of such efforts.

The Initiative has two intermediate objectives. The first is to reduce the supply of tobacco by limiting youth access to tobacco products. Implementation of comprehensive prevention and control activities, including enforcement of the FDA and Synar regulations is critical in achieving this objective.²⁶ The second intermediate objective is to reduce demand for tobacco products by

decreasing tobacco's appeal to youth and increasing the perceived harmfulness of tobacco use among young people. To focus attention on demand reduction, this Initiative covers the following five themes:

1. Promote positive alternatives to tobacco use through sports and youth centered activities;
2. Empower young people to address tobacco use among their peers;
3. Deglamorize tobacco use through a coordinated entertainment industry strategy;
4. Implement paid counter-advertising campaign to change social norms about tobacco use; and
5. Involve parents and families in addressing tobacco use among young people.

Although aggressive efforts are underway to successfully address these five themes, the Initiative is currently focused on cigarettes almost exclusively, with little attention on cigar usage among minors.

Healthy People 2000 Tobacco Progress Review

However, the Department's November 1997 *Healthy People 2000 Tobacco Progress Review* resulted in a follow-up item specifically addressing cigars. In response to the compelling data about the health risks of cigar smoking presented in the NCI monograph, the progress review challenges the Department with developing cigar-use prevention programs. Currently, prevention programs are underway in a few States, including California, New Hampshire, and Massachusetts. These States have taken steps to implement cigar use prevention messages through media campaigns or by distributing pamphlets.

Healthy People 2010 Objectives (Draft)

The current draft of the DHHS *Healthy People 2010 Objectives* includes a goal to reduce the proportion of young people in grades 9-12 who have used tobacco products. Reduction of cigar use among teens is included in these objectives. Specifically, the Department's proposed goal is to reduce past month cigar use from a high of 22 percent in 1997 among students in grades 9-12 to 9 percent by the year 2010. In order to reach the tobacco goals outlined in *Healthy People 2010*, the Department will focus on 1) preventing initiation of tobacco use; 2) promoting cessation of tobacco use; 3) reducing exposure to secondhand smoke; and 4) changing social norms and environments that support tobacco use.

METHODOLOGY

This study involved reviews of existing Federal regulatory authority and agency oversight responsibilities for cigars, along with systematic collection of information from all 50 States and the District of Columbia. While numerous published documents provided a historical perspective, many documents were obtained online via the Internet, allowing us to include the most recent information available. Additionally, we met with agency experts from the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA), and the Federal Trade Commission (FTC). Descriptions of the implementation of Federal laws by

agencies involved a synthesis of existing documentation and meetings with agency experts.

In addition to analyzing Federal laws and regulations, we collected information from contacts in each State that were deemed to be the most knowledgeable about Synar implementation. To determine the various State players involved in tobacco enforcement, we initially contacted the Single State Authority (SSA) from each State. The SSA's represent the agency receiving the Substance Abuse and Prevention Block Grant. In most cases, we were referred to one or more individuals who helped us obtain information about State tobacco laws and regulations, as well as ongoing enforcement activities. Our sources came from a variety of departments, but they more commonly came from the State Department of Public Health, Division of Drug and Alcohol Abuse, or Department of Health and Human Services. In several cases, data was collected from a variety of agencies and returned to us by an assigned contact person. All States and the District of Columbia responded to our request for information.

Although in some cases States were asked to submit documentation, the information presented in this report is primarily self-reported data. Some clarifying follow-up telephone calls were made to selected States. The information submitted to us is what the State contacts believe to be true in their State. To increase the readability of this report, we have substituted the word "States" when we mean "State contacts" and the District of Columbia.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

OVERVIEW

Cigars currently receive little oversight by Federal laws and regulations. Aside from advertising restrictions on little cigars, the only Federal oversight on cigars is through the Synar Amendment which requires States to have and enforce laws making it illegal to sell all tobacco products to minors, which would include the sale of cigars. As States have moved toward meeting the requirements of the Synar regulation, they have been encouraged to focus their compliance measurement on cigarettes.

The lack of emphasis on cigars is not surprising given the meager attention cigars have received from both the research community and the Federal government in prior years. Until recently, research regarding the potential health effects of using cigars and the prevalence of use among minors was extremely limited. The fact that cigars do not include a Surgeon General's warning label and are not part of the Food and Drug Administration's tobacco control regulations appears to be conveying an unintended message that cigars are not a public health concern.

We found States have generally adopted a similar attitude toward cigars, weakly enforcing their tobacco laws as applied to cigars. A large number of States currently do not have enough evidence to determine either the extent of cigar sales to minors or the ease with which they can purchase them. Nevertheless, those few States that are beginning to focus on this emerging issue have detected that minors are able to purchase cigars with the same ease as cigarettes.

FEDERAL LAWS

Cigars Have Not Faced The Same Degree Of Federal Regulation As Other Tobacco Products, Such As Cigarettes And Spit Tobacco.

Lack of Warning Labels on Cigars

Cigars are currently not required to include any Federal warning labels. This is not true for cigarettes and spit tobacco. As early as 1965, cigarettes were required to carry warning labels, but without mentioning the U.S. Surgeon General. In 1970, the language of cigarette warnings was strengthened, and revised warnings by the U.S. Surgeon General were mandated by Congress.²⁷ Spit tobacco products were first required to include rotational health warnings in 1986.

All cigar packages and boxes sold in California include a warning label. This is not true for individual cigars.^{28,29} The following warning label is required by California's 1986 Safe Drinking Water and Toxic Substances Enforcement Act, "Warning: This product contains/produces chemicals known to the state of California to cause cancer and birth defects or other reproductive harm." The warning is generic and appears on a variety of other non-tobacco products. Most manufacturers voluntarily include this warning on cigars sold in other States, but not all. Even where the warning is included, it is not always conspicuous.³⁰

Lack of Disclosure Requirements and Advertising Restrictions on Cigars

No Federal laws require cigar manufacturers to report the tar, nicotine, and carbon monoxide content of their products, nor have cigar manufacturers voluntarily disclosed their additives or developed protocols for doing so. Only Texas and Minnesota require nicotine reporting of cigars.³¹ Disclosures about tar, nicotine and carbon monoxide are collected by the Federal Trade Commission (FTC) and annually reported to Congress for cigarettes and spit tobacco products. Additionally, in 1994, cigarette and spit tobacco manufacturers voluntarily released lists of the ingredients added to the tobacco in cigarettes. The Department of Health and Human Services collects data submitted by tobacco manufacturers and importers on additives to cigarettes³² and spit tobacco,³³ however these data are aggregate and not brand specific. Cigar manufacturers have not released similar lists.

Prior to February 1998, the FTC did not require cigar manufacturers to submit any financial or sales information, as is required of manufacturers of cigarettes and spit tobacco. However, in February 1998, the FTC ordered the top five leading cigar manufacturers to file the number of cigars sold and amount spent on advertising, merchandising and promotion in 1996 and 1997.³⁴ In addition, they must submit a categorical breakdown of advertising and marketing expenses for each cigar brand and any money paid to motion pictures that featured the products. Under Section Five of the Federal Trade Commission Act, the FTC could require manufacturers to place health warnings in all advertisements if it had evidence that the failure to do so would deceive consumers or otherwise be “unfair.” This FTC authority was the source of health warnings on cigarette advertisements until the Comprehensive Smoking Education Act was enacted in 1984.

As for all product advertising, Federal and State truth in advertising laws require all cigar advertisements to be truthful and all claims made to be substantiated. Aside from the *Little Cigar Act of 1973*, there are no product specific advertising restrictions on cigars similar to those that exist for cigarettes and spit tobacco. Large cigars may be advertised in electronic media. Little cigars are the only type of cigars with an equivalent ban on broadcast advertising. Today, cigars are commonly sold on the Internet, with over 150 cigar websites selling or advertising cigars.³⁵ This new advertising medium now provides people of all ages exposure and access to cigars. The Cigar Association of America (CAA) adopted a voluntary guideline on responsible marketing practices in 1986 (“...cigar advertising should neither portray nor encourage use by individuals who are or appear to be below the age of 21”). However, a recent survey by the American Lung Association found that actors smoked cigars in 51 of 133 movies with at least a five million dollar domestic box-office draw each.^{36,37} Self-acknowledgment of product placement in movies and television by the CAA highlights that this voluntary guideline has not been strongly adhered to since it was put into place back in 1986. The CAA’s voluntary standards were amended in March 1998 to say that, “Cigar manufacturers should not subsidize the use of cigars in movies or television production through paid or donated cigar placements or otherwise.” The Association has stated it will “admonish” its members to discontinue the use of product placement.³⁸

Cigars Excluded from Food and Drug Administration’s Newest Tobacco Regulations

Effective in 1996, the Food and Drug Administration (FDA) began regulating cigarettes and spit

tobacco as nicotine-delivery devices under the Federal Food, Drug and Cosmetic Act (the Act).³⁹ The process the FDA went through to regulate these two products was both lengthy and cumbersome. To assert jurisdiction over cigarettes and spit tobacco, the FDA had to conduct an investigation to gather evidence that these products were drugs and/or devices as defined in the Act.⁴⁰ Although the health risks of smoking have long been known and the Surgeon General's warning label has existed since 1970, it was not until the early 1990's, that sufficient evidence existed enabling FDA to regulate cigarettes and spit tobacco under the Act.⁴¹ Beginning in the 1980's, a significant new body of evidence became available that established the addictive nature of nicotine in cigarettes and spit tobacco and provided a sound basis for the FDA to initiate a regulatory investigation. Not only did FDA conclusively determine that nicotine exerts mood-altering effects on the brain, but also that manufacturers intend for cigarettes and spit tobacco to be used for the pharmacological purpose of delivering nicotine.⁴²

FDA focused its investigation on cigarettes and spit tobacco products. FDA's rule making did not include cigars and pipe tobacco because the agency did not have sufficient evidence that these products are drug delivery devices under the Food, Drug and Cosmetic Act. Sufficient evidence was not available to the Agency when it wrote the proposed rule in 1995, nor when they issued the final rule in 1996, to show that manufacturers of cigars and pipe tobacco intend their product to affect the structure and function of the body like cigarettes and smokeless tobacco. In addition, available epidemiological evidence at that time showed that young people predominantly used cigarettes and spit tobacco. FDA remains open to initiating further investigations as new evidence becomes available and, "...the agency will consider any additional evidence that becomes available, including any new evidence that these products meet the statutory definitions, as well as evidence that indicates that cigars and pipe tobacco are used significantly by young people."⁴³

The first phase of FDA's regulation over cigarettes and spit tobacco became effective on February 28, 1997 when retailers were required to begin verifying the age of customers under age 27 by requesting a photographic identification including the purchaser's birth date. Retailers must not sell cigarettes or spit tobacco to persons under age 18.⁴⁴ As part of FDA's outreach effort, they will provide merchants with signs that can be displayed to inform potential cigarette and spit tobacco purchasers of this new regulation. To reduce the number of retail outlets selling these tobacco products to minors, FDA will contract with States to conduct retailer compliance checks. FDA's goal is to visit every tobacco retailer in every state at least once per year.⁴⁵ Where that is not possible, FDA seeks the maximum coverage possible. FDA is in the process of contracting with each of the States to conduct compliance checks. In Fiscal Year 1998, 41 States, plus the District of Columbia, signed contracts to inspect stores. FDA provided some retailers with a new advertising campaign reminding stores that they face fines if they sell cigarettes and spit tobacco to minors.^{46,47} Nevertheless, cigars are not included in the inspections because cigars are not covered by the FDA regulations. However, with the heightened attention on cigarettes and spit tobacco, there is a risk that merchants and consumers may overlook State laws enacted under the Synar regulation to restrict the sale of cigars to persons under age 18.

Lack of Cigar Focus in Implementation of the Synar Regulation

In response to the Synar Amendment, those States who had not already done so must enact laws

making it illegal to sell tobacco products to minors. Synar is currently the only authority granting Federal oversight over all tobacco products, including cigars. The Synar Amendment (section 1926) was added to the Public Health Service Act (42 USC 290aa) in 1992 to strengthen efforts to reduce the sale of all tobacco products to youth. States face the loss of significant amounts of Substance Abuse Prevention and Treatment block grant money if they do not show progress in reducing the sales of cigarettes to minors on a yearly basis. To implement Synar, States are required to use their own resources as Synar is not funded by Federal dollars. Although States are also required to enforce their own laws as applied to other tobacco products, including cigars, little is known by the Substance Abuse and Mental Health Services Administration (SAMHSA) about what is being done to enforce them.

SAMHSA currently requires States to conduct yearly, random, unannounced inspections to measure tobacco sales to minors and report their progress yearly to the Secretary of the Department of Health and Human Services. This is the only enforced Federal requirement addressing the Synar regulation. The current recommended methodology for conducting such inspections calls for purchase attempts by minors of cigarettes only, and not cigars or spit tobacco. In working with the States to develop an appropriate methodology for implementing the Synar Amendment, SAMHSA weighed several variables including the relatively high volume of cigarette use compared to cigar and spit tobacco use by minors and resource constraints faced by the States who do not receive Federal dollars to implement Synar. As a result of this analysis, SAMHSA chose to prioritize enforcement efforts and focus exclusively on cigarettes. Finally, SAMHSA encourages States to focus on cigarette sales to minors in order to establish a consistent measurement within each State.

SAMHSA has helped each State develop a statistically valid random sampling methodology with confidence intervals of 95 percent. Through random sampling, States establish a baseline rate for sales of tobacco products (cigarettes) to minors and then measure changes in that rate over time. States are required to use compliance checks to gather this data.⁴⁸ In implementing the Synar regulation as applied to cigarettes, States have faced a number of barriers. One of the biggest barriers in enforcing their tobacco laws is the lack of adequate resources for implementation efforts.⁴⁹ According to their FY 1998 SAMHSA Block Grant applications, 12 States report meeting the target of reducing to less than or equal to 20 percent, the percentage of retailers detected selling tobacco to minors in the annual Statewide surveys.⁵⁰ However, this target applies only to cigarettes. Under the current structure, States have no clear incentive to enforce their tobacco laws as applied to cigars or spit tobacco, although the Synar regulation requires this of States.

STATE LAWS, ENFORCEMENT, AND TRAINING

State Enforcement Of Laws And Regulations Prohibiting The Sale To, And Use Of Cigars By, Minors Is Currently Severely Limited.

All States (51) have tobacco laws broad enough to encompass cigars, with most explicitly stating that cigar sales to minors and their purchase, possession, and use of cigars are prohibited.⁵¹

All States and the District of Columbia not already having minors' access laws have addressed part of the Synar regulation by enacting or modifying laws or regulations restricting the sales and distribution of tobacco products to minors. In addition to Federal requirements, many States further restrict minors' access through laws that punish minors for either purchasing, possessing, or using tobacco products. In 33 States, it is illegal for minors to purchase tobacco products; in 26 States it is illegal for minors to possess tobacco products, while in 16 States it is illegal for minors to use tobacco products. Eleven States restrict tobacco advertising and seven States restrict the display of tobacco products.⁵² (See Appendix A for a complete State breakout.)

States also volunteered a number of additional restrictions they use to control minors' access to tobacco. Specifically, numerous States restrict vending machine placement.⁵³ Other State or local restrictions on tobacco products include: prohibitions on free or low cost distribution of tobacco products, tobacco restrictions at schools or sales close to schools, and billboard restrictions. Some States or localities also make it illegal to falsely represent one's age in order to purchase tobacco or to knowingly allow a person under age 19 to use tobacco in a place of business.

Seventeen States include a combination of four or more restrictions in their tobacco laws or regulations controlling minors' access to tobacco products. Texas currently prohibits the sale, purchase, possession, and use of tobacco products by minors; they also restrict the display and advertising of tobacco products.

However, States do not evenly enforce the laws and regulations that govern minors' access to tobacco. Cigars, in particular, currently receive a very low enforcement priority.

Over the years, States faced a number of barriers in conducting yearly, random, unannounced inspections to measure tobacco sales to minors. In particular, States have experienced difficulties in obtaining lists of tobacco vendors, which has increased the difficulty of performing inspections using scientific sampling.⁵⁴ In an effort to help States standardize their inspections across States and over time, SAMHSA encouraged States to focus their methodologies on inspections using cigarettes, to the exclusion of other tobacco products, such as cigars and spit tobacco. Currently, nearly all States have released baseline results from their unannounced inspections using minors to buy cigarettes as part of their latest SAMHSA block grant application. Beyond these yearly inspections, the Synar regulation also requires States to reduce the sale of all tobacco products to minors. Typically, States use compliance checks to measure the extent to which tobacco products are sold to minors in their State. Although States regularly use compliance checks for cigarettes, only 38 States reported using this method to restrict minors' access to spit tobacco. Even fewer States (27) reported using compliance checks for cigars, and of these, 16 States reported such

checks are rarely or seldom performed.

Forty-four States reported a variety of options for controlling minors' access to cigars, such as follow-up on complaints, compliance checks using minors, and observation of minors' attempted purchases. However, these methods are rarely or seldom applied.

Forty-four States reported having tools available that attempt to control minors' access to cigars. States were fairly candid, expressing, "Up until recently it has not been considered a priority," and, "Compliance checks focus on cigarettes." Three different methods were available to control minors' access to cigars, but States were fairly candid in reporting how infrequently their State applied any systematic enforcement mechanisms for cigars. The majority of States said they were not consistently applying any particular enforcement technique to cigars, while a few States were reluctant to answer questions about how frequently these techniques are used in their State.

- ▶ *Follow-up on Complaints:* Of the methods mentioned, the most frequent was the passive method of State follow-up on any complaints received. Of the 29 States mentioning this method, 12 said it is rarely applied to control minors' access to cigars, another 4 States said they seldom used it, and 5 States said they used it sometimes.⁵⁵ Nevertheless, seven States reported always using follow-up on complaints of cigar sales to minors as a method to control access. One State reported using this method but failed to disclose how often it is applied to cigars.
- ▶ *Minor Compliance Checks:* Although all States should be using compliance checks for the purposes of measurement to comply with the Synar regulation, only 27 States report using minors for cigar purchase compliance checks to control cigar access.^{56,57} However, ten States rarely applied this technique to cigars, six seldom applied it, and seven States only sometimes applied this method. Only two States said they always utilized compliance checks using minors to purchase cigars. In follow-up conversations, one of these States reported they do not differentiate tobacco products, but assume that enforcement is always applied to cigars. This State reported there is no way to either calculate how many compliance checks target cigars or the number of complaints their State receives regarding illegal cigar sales. This State's assumption paralleled information reported by other States. Two States did not report how often this method was used.
- ▶ *Observation of Attempted Purchases:* A less common method of controlling cigar access by minors was observing minors' attempted cigar purchases. Of the 16 States using this method, 4 reported they rarely apply this technique to cigars, and 9 sometimes do. Only three States reported they always apply this method to cigars.
- ▶ *States Not Currently Attempting to Control Minors' Access to Cigars:* Seven States do not attempt to control minors' access to cigars. States explained this is because they are currently concentrating on other tobacco products, such as cigarettes and spit tobacco.

As one State explained, "In this early stage of enforcement, we are focusing on the most serious problem - cigarettes, which are the primary source of adolescent and adult health problems. As our experience and effect increases, we will add smokeless tobacco, and, finally, cigars to

enforcement activities.” Likewise, another State said, “Technically, cigars are controlled by laws; however, enforcement activities have thus far focused on other tobacco products.”

Statewide training of tobacco merchants, as well as information about these merchants, is limited. For example, while 36 States require a license or permit to sell tobacco, the majority of States could not provide a list of merchants selling cigars because they do not require merchants to specify the type of tobacco products sold.

The majority of States (35 States) provide some training for merchants selling tobacco products. Only 11 States do this statewide, while 12 additional States conduct such training for some tobacco merchants. The remaining States provide merchant training in targeted areas only or upon request, and/or provide information in merchant packets. Only 19 States reported specifically telling merchants that they are prohibited from selling cigars to minors. Thirty-six States require a license or special permit for tobacco retailers in general.⁵⁸

In order for States to conduct tobacco compliance checks of merchants using random sampling, they must obtain a list of all merchants selling tobacco products in their State. However, as States have addressed SAMHSA’s and FDA’s methodology for conducting compliance checks for cigarettes, they have experienced a number of barriers. One barrier is obtaining a statewide list of merchants selling tobacco, while another barrier is determining which merchants sell cigarettes. With the emergence of specialized cigar shops, States have attempted to eliminate these merchants from their lists because SAMHSA’s and FDA’s approved methodologies only include compliance checks using cigarettes. Because most States’ licensing and permits do not require merchants to specify which tobacco products they sell, States often can only determine this information by visiting the merchant’s shop or through review of excise tax information.

While the lack of specific tobacco information has been problematic for cigarettes, it also presents a problem for States trying to obtain cigar sales information from merchants. Seventeen States could not obtain a list of all merchants who sell cigars in their State, while one State did not know if their State could obtain this information. Only eight States say they could provide a list of merchants who sell cigars in their State. However, four of these States mentioned that it would be a more general list of those selling any type of tobacco, including cigars. Three States said they could not list all cigar merchants because their list of vendors is also not broken down by the type of tobacco product sold.

Twenty-five States report providing public education regarding cigar use, but most appear to only address tobacco in general. However, three States are currently using or planning to use public service announcements or media campaigns that specifically address the dangers of cigar use.

Nearly half (25) of States said they provide public education regarding cigar use, with 14 States providing this education on an ongoing basis. However, it was unclear how many of these States focused on tobacco in general, rather than specifically mentioning cigars in their public education efforts. We ascertained that three States are currently using or planning to use public service announcements (PSA’s) or media campaigns specifically focused on cigars. Based on a survey of

boys and girls in two New York counties which found widespread cigar use, the State now runs PSA's aimed specifically at cigar usage and teens. They developed three separate PSA's ranging from 10 to 30 seconds in length that address the hazards of cigar smoking. Their 30 second PSA says,

“In movies and magazines, good times and cigars often seem to go together. But that’s not the whole story. Behind the smokescreen of false glamour, cigars cause bad breath and stained teeth, just as cigarettes do. And don’t forget what the smell of stale cigar smoke does to your clothes and hair. What else you don’t see in the billows of cigar smoke are the nicotine and other poisons. Even if you don’t inhale, cigar smoke can cause cancer of the lung, mouth and throat. The poisons in cigar smoke can also lead to heart and lung disease. The (county health agency name) says: Behind the smokescreen, there is nothing but smelly, poisonous smoke.”

The State of California has developed a statewide media campaign addressing the myth that cigars are safer than cigarettes because cigar smoke is not inhaled.⁵⁹ With kids as young as 12 and 13 experimenting with cigars in California, they found the necessity to increase awareness about the serious health hazards of cigar smoking. The campaign includes a television commercial and radio advertisement. As stated by California’s Health Department director, “We anticipate that the somewhat humorous tone of the two ads will attract the attention of teens and young adults, and that they’ll also get the serious message that cigars are more than fashionable -- they’re life threatening.” The Massachusetts Department of Public Health has developed a 30 second television spot, 60 second radio spot, and a poster to illustrate to youth that the tobacco industry and media are manipulating them.⁶⁰ This new campaign will air statewide to counter the cigar exposure kids are receiving in movies, television shows, and music videos. Their television spot is filmed very much like a popular music video, using an “industry rap” to highlight how the industry tries to persuade black kids to smoke cigars. The spot closes with the phrase, “Don’t let the tobacco companies play you.” The 60 second radio ad also uses a tobacco industry guy rapping a tune. The rap song begins with, “We know you people well, we know what to do. You see rappers with cigars, you want to smoke ‘em too.”

Although delivering a similar message about the dangers and effects of cigar smoking, all three States have chosen somewhat different target audiences. Clearly, States will need to keep in mind the diversity among cigar users and develop anti-cigar media campaigns that capture the attention of as many of these groups as possible. The three States conducting public education campaigns are good examples of how to counter the glamorous message currently being delivered in movies, television, and the media.

Many States lack a general awareness about the extent of cigar sales to minors, the ease with

which minors can purchase cigars, and the degree to which minors' use of cigars is a problem in their State.

With few State controls to enforce tobacco laws and regulations as applied to cigars, it should not be surprising that States lack a general awareness about the extent of cigar sales to minors. Twenty-two States admit they do not know the extent of cigar sales to minors. Three States reported cigar sales to minors were a serious problem in their State, while five reported they were a moderate problem. Another 13 States reported cigar sales to minors as a minor problem. Only one State said cigar sales to minors was not a problem in their State.

Of the seven States reporting that cigars are not currently included in their control or enforcement activities, five States said that they do not know the extent of the problem of cigar sales to minors, while one State said they viewed it as a moderate problem and one said it was a minor problem. Only four States were aware of any completed studies of the use of cigars by minors or young adults in their States. For example, California specifically asks youth (12-17 years old) about the prevalence of cigar use in their annual tobacco phone survey, and Massachusetts asks their students about lifetime and current cigar use. Six other States report plans for such studies at the State (5) or local (1) level. These States plan to incorporate specific cigar questions into an existing youth survey.

Those few States mounting active attempts to control minors' access to cigars report they are detecting that minors can purchase cigars with the same ease as cigarettes.

Twenty-two States do not know how easily minors can purchase cigars, as compared to cigarettes. However, of the 13 States more actively controlling minors' access to cigars by using three or more control methods, the majority (9 States) report that minors can purchase cigars with the same ease (8) or even somewhat greater ease (1) than they can buy cigarettes.⁶¹ Of the 31 States currently using less than three control methods to control minors' access to cigars, the majority (19) do not know the ease of cigar purchases compared to cigarette purchases.

BARRIERS TO CIGAR ENFORCEMENT

Lack Of Resources And Low Enforcement Priority Are Seen As The Most Significant Barriers To Effective Control Of Cigar Use By Minors.

State contacts listed a number of barriers to the effective enforcement of cigar laws and regulations restricting access to minors. The biggest barriers, listed by 31 State contacts, dealt with insufficient resources for enforcement and/or a general unwillingness by the community and local law authorities to prioritize enforcement. It should be noted that the Synar enforcement requirements are an unfunded State mandate. Many State contacts reported struggles in enforcing their tobacco laws, in general, while a few State contacts mentioned specific barriers to cigar and spit tobacco enforcement.

A few typical comments related to this barrier included: “The issues regarding enforcement are virtually the same regardless of the type of tobacco. Those issues include: lack of recognition of the seriousness of the problem and lack of coordinated enforcement efforts;” and “At this time there is a lack of resources within the State to adequately address cigar usage separately. However, the coming trend and increased availability lead the State to believe that this product will need separate attention in the future.”

Secondary to low priority and resource constraints, 13 State contacts listed a lack of awareness of the dangers of cigar usage and the extent of minors’ usage in their State as a major barrier. One contact typified this barrier by saying, “Both cigars and smokeless tobacco have not been viewed as serious health risks. The primary focus has been on cigarettes.”

Additional barriers listed by State contacts include problems with retailers (12 States), such as failing to enforce the laws, placement of cigars in accessible locations, and the lack of licensing. Illustrative responses included: “Clerks typically associate teen tobacco use with cigarettes only. Thus, sales are more likely to occur when it comes to cigar or smokeless tobacco use;” and “We are seeing an increase in cigar use as enforcement on cigarettes and retailer awareness grows.”

Lastly, five State contacts list industry marketing practices linking cigars with glamour and success, as well as product placement in youth-oriented movies and TV shows as barriers to enforcement. The lack of inclusion of cigars in the FDA regulations is also mentioned as a barrier by four State contacts. Eighteen State contacts recommend that cigars should be included in the FDA regulations.

RECOMMENDATIONS

Our study focused on the application of Federal and State laws and regulations aimed at restricting youth access to cigars. We found that the shield of protection in place for other tobacco products is largely missing for cigars. As part of our background research, we learned that much new knowledge about cigars and cigar use has become available since the development of the regulations implementing the Synar Amendment and FDA's rule on cigarettes and spit tobacco. Much of that new information is highlighted in NCI's cigar monograph. When combined with the additional insights profiled in our companion report on the use of cigars by teens, we feel that sufficient evidence exists to warrant the Department to address the emerging health risks of cigar usage.

We recognize that when compared to the existing knowledge on cigarette use and addiction there is still much to learn about cigar usage. Different tobacco products and delivery forms may pose different health risks and this should guide development of policy and regulation. However, these differences should not prevent the Department from assessing and appropriately responding to this emerging public health risk.

Given what we already know about the health risks of cigars, the step-up in advertising and glamorization of the product, the susceptibility of youth to such inducements, the surprisingly high levels of cigar use by youth, and the widespread phenomenon of "blunting" cigars for marijuana consumption, we recommend that the various components of the Department (CDC, FDA, NIH, SAMHSA, ASPE, etc.) under the leadership of the Assistant Secretary for Health develop an action plan to address the public health risks posed by cigar use, particularly access by youth.

As a first step, we recommend an initiative to inform the public about the health risks associated with cigar smoking. The Assistant Secretary for Health is well positioned to help the appropriate agencies within the Department develop a public awareness and health risk educational effort appropriate for cigars. This public effort would support the Department's *Healthy People 2010* goal (draft) to, "reduce the proportion of young people in grades 9-12 who have used tobacco products." For cigars, the goal is to reduce youth use from a high of 22 percent in 1997 to 9 percent by 2010. This effort could include pursuing a collaborative effort with the Federal Trade Commission and Congress to initiate a Surgeon General's Warning Label for cigars.

Second, the Department should address the need for additional research on cigars, including prevalence, patterns of use, youth access and ease of purchase, health effects, the addictive potential of cigars, and the practice of "blunting," or using cigars to smoke marijuana. This initial effort should specifically address the adequacy of the Department's data collection and survey capacity for monitoring trends in cigar use and whether to incorporate additional questions on cigar usage into existing Departmental school-based, household and other ongoing surveys of tobacco and drug usage.

Data gleaned from this research agenda may provide information that will enable the Department to refine the action plan and address more specific issues such as how best to expand enforcement efforts under the Synar Amendment to address cigars, including identifying resources needed to

accomplish this, and whether FDA should initiate the investigatory process for asserting jurisdiction over cigars comparable to that exercised by the FDA over cigarettes and spit tobacco and/or have Congress expressly affirm FDA's authority to regulate cigars.

ENDNOTES

1. The cigar prevalence information reported by CDC came from the Robert Wood Johnson Foundation's (RWJF) 1996 National Study of Tobacco Price Sensitivity, Behavior, and Attitudes Among Teenagers and Young Adults.

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. "Cigar Smoking Among Teenagers - United States, Massachusetts, and New York, 1996." *Morbidity and Mortality Weekly Report (MMWR)*. May 23, 1997. 46: Online. Internet.

2. Data from a 1996 survey by the Massachusetts Department of Public Health of high school and junior high school students.

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. "Cigar Smoking Among Teenagers - United States, Massachusetts, and New York, 1996."

3. Data from a 1996 survey by the Massachusetts Department of Public Health of high school and junior high school students.

U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute. *Cigars: Health Effects and Trends, Smoking and Tobacco Control*. Monograph Number 9, April 1998.

4. Data from the 1996 California Tobacco Survey.

News Release. California Department of Health Services. "California Launches Public Awareness Campaign Targeting the Increase in Cigar Use," March 30, 1998.

5. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. "Tobacco Use Among High School Students -- United States, 1997." *Morbidity and Mortality Weekly Report (MMWR)*. April 3, 1998. 47: No. 12.

6. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. "Tobacco Use Among High School Students -- United States, 1997."

7. Data from SAMHSA's 1997 National Household Survey on Drug Abuse (NHSDA) shows current past month cigar use for 12-17 year olds to be only 5 percent. One of the biggest discrepancies in the Youth Risk Behavioral Survey (YRBS) data and the NHSDA data is the methodology used to collect the data. The 1997 YRBS data is based on a representative sample of 16,262 students in grades 9-12 in the 50 States and the District of Columbia. The 1997 NHSDA data is based on a household survey of 24,505 respondents

including 7,844 young people aged 12-17. The NHSDA cigar data is obtained through a self-administered questionnaire taken by the child. While every effort is made to afford the child privacy in the interview, the child's parent may or may not be in the room during the interview. Additionally, the NHSDA cigar questions were located in a "non-core" section of the 1997 questionnaire that also inquired about needle use and other hard core drug use. The YRBS cigar questions are located in a separate section about tobacco use. These two differences could help explain some of the discrepancies in the two sources of data. Beginning in 1999, the NHSDA will be administered using computer assisted technology. Also in 1999, the NHSDA questionnaire will include cigar questions in a separate section with other tobacco use.

8. Data from the Roswell Park Cancer Institute's 1996 Survey of Alcohol, Tobacco, and Drug Use in two New York counties.

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. "Cigar Smoking Among Teenagers - United States, Massachusetts, and New York, 1996."

9. Klein, Alec. "The Shaping of an Illusion," *The Baltimore Sun*, Sunday, January 11, 1998. Online. Internet.
10. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. *Reducing the Health Consequences of Smoking: 25 Years of Progress - A Report of the Surgeon General*. DHHS Publication Number (CDC) 89-8411, 1989.
11. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute. *Cigars: Health Effects and Trends, Smoking and Tobacco Control*. Monograph Number 9, April 1998.
12. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute. *Cigars: Health Effects and Trends, Smoking and Tobacco Control*. Monograph Number 9, April 1998.
13. The monograph does not formally define "regular" cigar smoker. However, a "regular" cigar smoker commonly refers to a person who smokes cigars 3-4 times a week.
14. This data is based on the Cancer Prevention Study I of the American Cancer Society. This prospective cohort study was conducted between 1959 and 1972 and followed more than one million individuals for twelve years. The age-standardized rate ratio of lung cancer for primary cigar smokers compared to neversmokers varied from 0.9 to 3.40 depending on the number of cigars smoked per day. The combined rate ratio was 2.10 for all levels of cigar smokers. The age-standardized rate ratio of mouth and throat cancer for primary cigar smokers compared to neversmokers varied from 2.12 to 15.94 depending on the number of cigars smoked per day. The combined rate ratio was 7.92 for all levels of cigar

smokers.

15. Company Press Release. "New Study Casts Cloud Over Trendy Tobacco Product: Cigar Smokers at Increased Risk of Death," Thursday, March 19, 1998. Online. Internet.
16. *The Washington Post*, March 21, 1998. Online. Internet.
17. Ibid.
18. Ibid.
19. One of the world's largest cigar companies, Swisher International Group, Inc. reported a 73 percent increase in net income for the fourth quarter of 1997. Although higher unit sales and pricing for both cigars and smokeless tobacco were responsible for such increases, cigar unit sales were up 12 percent or over 40 million units. Swisher International Group, Inc. produces a variety of machine-made cigar product lines including 10 different types of Swisher Sweets and 12 types of King Edward cigars. Company Press Release. "Swisher International Group, Inc. reports 73 percent Increase in Fourth Quarter 1997," Thursday, February 5, 1998. Online. Internet.
20. Consolidated Cigar Holdings, Inc. reported a net sales increase of 80 percent from the fiscal year ending 1997 compared to 1996. The company held a continued trend of premium and mass-market cigars responsible for this growth.
21. News Release. California Department of Health Services. "California Launches Public Awareness Campaign Targeting the Increase in Cigar Use," March 30, 1998.
22. Fermented tobacco leaves and a tobacco wrapper (versus paper) are two characteristics distinguishing cigars from cigarettes.
23. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute. *Cigars: Health Effects and Trends, Smoking and Tobacco Control*. Monograph Number 9, April 1998.
24. Swisher International recently added *Swisher Blunts* to their product-line, while Phillies added *Phillies Sweets* to their already popular *Phillies Blunt* product-line.
25. An example highlighted in the OIG study (OEI-06-98-00030), is the May 1998 cover of *Vibe* magazine which features rapper/hip-hop success Master P with a cigar in his mouth.
26. The Public Health Service Act (42 USC 290aa) was amended in 1992 by the Synar amendment (Section 1926) to strengthen efforts to reduce the sale of all tobacco products to youth.
27. In 1965, the generic cigarette health warning read, "Caution: Cigarette Smoking May Be Hazardous to Your Health." However, in 1970 the strengthened warning on cigarette packages read, "Warning: The Surgeon General Has Determined That Cigarette Smoking

- Is Dangerous to Your Health.” U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. *Reducing the Health Consequences of Smoking: 25 Years of Progress - A Report of the Surgeon General*.
28. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute. *Cigars: Health Effects and Trends, Smoking and Tobacco Control*. Monograph Number 9, April 1998.
 29. As a result of a 1988 lawsuit, the State of California requires that tobacco products carry a warning label on the retail package, but not the individual cigars. Some manufacturers include the required warning label on a sticker for cigar distribution in California only, while several manufacturers actually place it on the retail package. In the case of many premium cigars, this warning label is found on the inside of cigar boxes.
 30. Often, the warning label uses very small print and is located on the side of the cigar box. Some manufacturers also place the label on a very dark background which makes it especially difficult to see.
 31. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute. *Cigars: Health Effects and Trends, Smoking and Tobacco Control*. Monograph Number 9, April 1998.
 32. Federal Cigarette Labeling and Advertising Act. 15 U.S.C., 1335a, Section 7, Cigarette Ingredients.
 33. Comprehensive Smokeless Tobacco Health Education Act of 1985. 15 U.S.C., 4403, Section 4, Ingredient Reporting.
 34. The Associated Press. “FTC Wants Cigar Maker Finance Data,” *The Washington Post*, February 9, 1998. Online. Internet.
 35. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute. *Cigars: Health Effects and Trends, Smoking and Tobacco Control*. Monograph Number 9, April 1998.
 36. Cigar Association of America publication. *Banding Together: Keeping Cigars Away From Kids*. 1998.
 37. The Associated Press. “Cigars to Have Fewer Movie Roles,” *The Washington Post*, March 21, 1998. Online. Internet.
 38. Ibid.
 39. Federal Register/Vol. 61, No. 168/Wednesday, August 28, 1996/Rules and Regulations, page 44423. 21 CFR Part 801, et al. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule.

40. According to the Act, a drug is defined as “A . . . (2) an article (other than food) *intended to affect the structure or any function of the body of man or other animals*. “The Act’s device definition parallels the drug definition and provides that an instrument, apparatus or other similar article is a device if it is . . . (2) *intended to affect the structure or any function of the body of man or other animals*.” Using these criteria, FDA proved that the nicotine in cigarettes and smokeless tobacco is a drug and that cigarettes and smokeless tobacco are drug delivery devices whose effect their manufacturers intend.
 41. Federal Register/Vol. 61, No. 168/Wednesday, August 28, 1996/Rules and Regulations, page 44423. 21 CFR Part 801, et al. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule.
 42. It has been conclusively determined that nicotine exerts mood-altering effects on the brain and that it motivates repeated, compulsive use which creates dependence in the user; nicotine delivered by cigarettes and spit tobacco causes and sustains addiction. In addition, nicotine causes other drug-effects such as producing tranquilizing or arousal-inducing effects on the body, and induces weight loss. Evidence obtained from the release of internal tobacco company documents confirms evidence developed by independent researchers that cigarettes and spit tobacco affect the structure or any function of the body and that manufacturers intended that these effects occur.
- FDA found three types of objective evidence provide independent bases for finding that cigarette and spit tobacco manufacturers intend for their products to affect the structure or any function of the body: (1) the evidence of foreseeable pharmacological effects and uses of cigarettes and spit tobacco; (2) the evidence of actual consumer use of cigarettes and spit tobacco for pharmacological purposes (e.g., drug effects); and (3) the evidence of the statements, research, and actions of the manufacturers themselves that they understand that consumers use cigarettes and spit tobacco to obtain the pharmacological effects of nicotine and that they design their products to provide a pharmacologically active dose of nicotine. When considered independently or cumulatively, this evidence convincingly demonstrates that their manufacturers intend for cigarettes and spit tobacco to be used for pharmacological purposes.
43. Federal Register/Vol. 61, No. 168/Wednesday, August 28, 1996/Rules and Regulations, page 44423. 21 CFR Part 801, et al. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule.
 44. MedicineNet News. “Tobacco Regulation and the FDA,” September 5, 1997. Online. Internet.
 45. In the first year of the program (1998), FDA expects to visit one-third of the nation’s tobacco retailers and conduct between 100,000 - 200,000 compliance checks. Starting with the third year of the program, FDA expects to visit 80 percent of all tobacco retailers and to conduct a half million compliance checks annually. Once compliance checks identify retailers in violation of its regulations, FDA begins enforcement actions. For a first violation, FDA sends the retailer a letter explaining the new regulations, describing the

violation and informing the retailer that another compliance check will be scheduled. With a second violation, FDA assesses a civil money penalty of \$250 which escalates upwards from \$1,500 for the third violation to \$10,000 for a fifth violation within 36 months. Funds to conduct follow-up compliance checks for violators will come from the total funds contained in each State's contract with FDA.

46. The Associated Press. "U.S.: Teen Tobacco Sales Persist," *The Washington Post*, February 27, 1998. Online. Internet.
47. The eleven States with FDA contracts are Arkansas, California, Colorado, Florida, Illinois, Massachusetts, Minnesota, North Carolina, Pennsylvania, Texas, and Washington.
48. To develop their random sample of tobacco retailers, States typically divide the State into regions, and within each region either develop their sample using the established list of licensed vendors within the State. If such a list is not available, States use a commercial list or work from a stratified random sample of zip codes within each region and visit every retailer in those identified zip codes.

SAMHSA has worked with each State to develop sampling methodology, set goals for reducing the rate of sale of tobacco products to minors and set a timeline for achieving a rate of sale under 20 percent by the year 2002. If a State fails to meet those goals, Synar regulations require that SAMHSA reduce the amount of the Substance Abuse Prevention and Treatment Block Grant paid to the State.

49. Jacobson, Peter D. and Jeffrey Wasserman. *Tobacco Control Laws: Implementation and Enforcement*. RAND, Santa Monica, CA. 1997.
50. Data provided by SAMHSA's Center for Substance Abuse Prevention. November 1998.
51. All data provided is self-reported by experts in each State deemed the most knowledgeable about tobacco enforcement. Our survey instrument inquired about both State laws and regulations. Differences exist with the CDC because our information includes State regulations and theirs does not. The biggest difference exists in the information presented in the following section. According to CDC, most States do not explicitly list cigars as part of the definition of tobacco. In fact, only 23 States do. Of those 23 States, only five prohibit the purchase, possession, and use of tobacco products, including cigars. Fourteen States offer some combination of access restrictions (such as purchase only or possession only). The final three States do not offer any purchase, possession, or use language in their access laws.
52. Although information reported about State laws was self-reported by contacts deemed knowledgeable about tobacco control in each State, we cross-checked this information with information collected by CDC as of March 31, 1998. We also followed up with selected States and CDC to resolve any discrepancies.
53. We did not specifically ask about vending machine restrictions in our survey. However, 11 States mentioned they have restricted vending machine placement. CDC's

November 3, 1995 *MMWR* reported 37 States had laws in place addressing vending machines.

54. U.S. Department of Health and Human Services, Office of Inspector General, Office of Evaluation and Inspections. *State Oversight of Tobacco Sales to Minors*. OEI-02-94-00270. April 1995.
55. A five-point scale was used by State respondents to describe how often methods to control minors' access to cigars are applied in their State. The scale included: always, very frequently, sometimes, seldom, and rarely.
56. Using minor compliance checks as an enforcement measure implies there is some sort of penalty either to the clerk or the store related to the sale of a tobacco product to minors. An important measure of the enforcement of minors' access laws is the number of fines or tickets given as a result of illegal tobacco sales to minors. The goal of enforcement is a reduction in the percentage of retailers willing to sell tobacco to minors, and ultimately a reduction in the percentage of youth who use tobacco products in order to decrease morbidity and mortality related to tobacco use. Unfortunately, this information is usually not available or recorded centrally by the State.
57. There are two purposes for compliance checks of tobacco sales to minors. One is for measurement purposes and one is for enforcement. In order to meet the requirements of the Synar regulation, States are required to use compliance checks to gather the rate of sale for tobacco products (cigarettes) to minors. Compliance checks used for measurement purposes do not identify and penalize individual retailers who sell tobacco to minors. However, compliance checks used for the purposes of enforcement identify retailers who sell tobacco to minors. Although penalties vary by State for such sales, most States have escalating fines for repeat violations.
58. CDC found that 36 States had laws in place as of March 31, 1998 that required licensing of tobacco products in general. However, only 28 States reported to us that they required a license or special permit for cigar retailers.
59. News Release. California Department of Health Services. March 30, 1998.
60. Massachusetts Department of Public Health. Media correspondence. April 6, 1998.

61. Table 1 below illustrates that those States more actively controlling minors' access to cigars also reported minors can purchase cigars with the same ease or even somewhat greater ease than they can buy cigarettes. Although we do not know why this relationship exists, we suspect the States with more controls in place have done more to learn about the cigar sales to minors and were more in touch with the extent of the problem.

Table 1: Number of Methods Used to Control Minors' Access To Cigars by Ease of Minors' Cigar Purchase vs. Cigarette Purchase					
Ease of Minors' Cigar Purchases Compared to Cigarettes					
Number of Tobacco Control Methods Used	Somewhat or Much Easier	About the Same	Somewhat or Much Harder	Don't Know	Total* States
< 3 Control Methods Used	3% (1)	23% (7)	13% (4)	61% (19)	100% (31)
> 3 Control Methods Used	8% (1)	61% (8)	8% (1)	23% (3)	100% (13)

* Note: Only 44 States report controlling minors' access to cigars.

APPENDIX A

STATEWIDE TOBACCO LAWS						
	Sale to Minors Illegal	Illegal for Minors to Purchase	Illegal for Minors to Possess	Illegal for Minors to Use	Display Restrictions	Advertising Restrictions
Alabama	✓	✓	✓	✓		
Alaska	✓		✓			
Arizona	✓	✓	✓			
Arkansas	✓					
California	✓	✓	✓			✓
Colorado	✓	✓				
Connecticut	✓	✓				
Delaware	✓	✓				
District of Columbia	✓				✓	
Florida	✓	✓	✓		✓	
Georgia	✓	✓				
Hawaii	✓	✓				
Idaho	✓	✓	✓	✓		
Illinois	✓	✓				✓*
Indiana	✓	✓	✓			
Iowa	✓	✓	✓	✓		
Kansas	✓	✓	✓			
Kentucky	✓	✓				✓*
Louisiana	✓	✓	✓			✓*
Maine	✓	✓	✓	✓		
Maryland	✓		✓	✓		
Massachusetts	✓					

	Sale to Minors Illegal	Illegal for Minors to Purchase	Illegal for Minors to Possess	Illegal for Minors to Use	Display Restrictions	Advertising Restrictions
Michigan	✓		✓*	✓*		✓*
Minnesota	✓	✓	✓	✓	✓	
Mississippi	✓				✓	
Missouri	✓					
Montana	✓		✓	✓		
Nebraska	✓			✓		
Nevada	✓					✓*
New Hampshire	✓	✓	✓	✓*		
New Jersey	✓					
New Mexico	✓	✓				
New York	✓					
North Carolina	✓	✓				
North Dakota	✓			✓		
Ohio	✓					
Oklahoma	✓	✓	✓			
Oregon	✓		✓			
Pennsylvania	✓					✓*
Rhode Island	✓	✓		✓*		
South Carolina	✓					
South Dakota	✓	✓	✓	✓		
Tennessee	✓	✓			✓	✓*
Texas	✓	✓	✓	✓	✓	✓
Utah	✓	✓	✓			✓
Vermont	✓	✓	✓		✓	
Virginia	✓	✓	✓			
Washington	✓	✓				

	Sale to Minors Illegal	Illegal for Minors to Purchase	Illegal for Minors to Possess	Illegal for Minors to Use	Display Restrictions	Advertising Restrictions
West Virginia	✓		✓	✓		✓
Wisconsin	✓	✓	✓			
Wyoming	✓	✓	✓	✓		
TOTALS	51	33	26	16	7	11

* All State self-reported information was cross-checked with CDC. Noted changes reflect CDC's information dated 3/31/98.