REPORT OF THE
DEPARTMENT OF ALCOHOLIC
BEVERAGE CONTROL ON

TOBACCO LAW ENFORCEMENT IN VIRGINIA: A REVIEW OF RESOURCE ALLOCATION REQUIREMENTS FOR THE DEPARTMENT OF ALCOHOLIC BEVERAGE CONTROL

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

SENATE DOCUMENT NO. 24

COMMONWEALTH OF VIRGINIA
RICHMOND
1998

COMMONWEALTH of VIRGINIA

Department of Alcoholic Beverage Control

2901 HERMITAGE ROAD
P.O. BOX 27491
RICHMOND, VIRGINIA 23261
(804) 213-4400
FAX: (804) 213-4411
HDD LOCAL (804) 213-4687

MEMORANDUM **December 31, 1997**

To: **The Honorable George Allen**

From: **Clater C. Mottinger** Clater C. Mottinger

Subject: **Tobacco Law Enforcement in Virginia: A Review of Resource Allocation Requirements for the Department of Alcoholic Beverage Control**

As mandated by the 1997 Virginia General Assembly, the Department of Alcoholic Beverage Control is submitting the report "Tobacco Law Enforcement in Virginia: A Review of Resource Allocation Requirements for the Department of Alcoholic Beverage Control."

If you have any questions or need additional information, please do not hesitate to contact me.

CCM:ah

cc: **Bruce F. Jamerson, Clerk of the House**
Susan Clarke Schaar, Clerk of the Senate

The Honorable E. Montgomery Tucker
Secretary of Public Safety

Purpose of the Report

Key Legislation Passed in 1997 Virginia General Assembly
During the 1997 General Assembly, several bills were passed that increased enforcement of the Commonwealth's underage tobacco laws. House Bill 2530 and its identical companion, Senate Bill 1162 (See Appendix 1 for copy of legislation), specifically allocated to the Department of Alcoholic Beverage Control (ABC), the authority to enforce the Commonwealth's underage tobacco laws. The bills also doubled the penalties for those convicted of selling tobacco to minors and for minors convicted of possession. The legislation directs ABC to *'report any additional fiscal and manpower needs necessary to comply with the provisions of this section to the Governor and the General Assembly in December 1997 and December 1998."*

The extent that additional resources will be required depends on the scope of the ABC's authority and the level of federal support. This document will identify key issues related to tobacco law enforcement at both the state and federal levels. The report will also identify the additional resources required under the various scenarios.

Key Federal Issues

Increased Federal Attention
In the last four to six years, the issue of underage access to tobacco has received increased attention at the federal level. Increased regulation and mandates combined with the threat to reduce funding, have resulted in additional workloads for states. This section will provide a brief overview of the key federal activities.

Synar Amendment
Passed in 1993, the Synar Amendment to the Public Health Service Act of 1992 required states to prohibit sales to those under 18 and to enact measures to prevent such sales. The critical part of the act is the threat to reduce block grant funds if states do not comply with federal law. The final regulations implementing this act were issued in January 1996. As a result of the final rules, states are required to: 1) Pass laws restricting the sale of tobacco products to minors, 2) Determine the percentage of retailers that are not in compliance with state

law, 3) Complete annual compliance checks to assess change from baseline, and 4) Submit a five to seven year plan that describes how the state will reduce its sales rate. A significant portion of the state's substance abuse treatment block grant funds can be withheld if the Department of Health and Human Services feels that a state has not made significant progress (See Appendix 2 for additional information about the Synar Amendment).

Synar Compliance in Virginia

In Virginia, the Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS) is responsible for reporting Synar compliance. They currently contract with the Department of Health (DOH) for conducting the necessary compliance checks and report generation (amount not available). Since DOH does not have enforcement agents, they use a vast array of local volunteers to conduct compliance checks. The first checks, completed in 1996, established a baseline of 36.9% of merchants that were non-compliant. In addition to the on-site surveys, this program also includes a comprehensive merchant and community education campaign. In 1997, DOH coordinated 733 compliance checks with 238 found to be non-compliant.

FDA Regulations

In 1996, President Clinton approved federal regulations that declare nicotine a drug, giving the FDA specific authority to regulate 'nicotine delivery devices." In August 1996, the FDA issued extensive regulations concerning the sale of tobacco products. These included restrictions on marketing, advertising, packaging and prescribed federal penalties for violation. The authority of the FDA to regulate tobacco was challenged in court by the tobacco industry. In April 1997, the court upheld the FDA's authority to regulate tobacco but struck down its ability to regulate advertising. Both sides have appealed and the matter is currently before the Fourth Circuit Court of Appeals (See Appendix 3 for additional information about FDA regulations and legal issues).

Enforcing the FDA Regulations in Virginia

The FDA is currently seeking to contract with enforcement entities in each state to conduct tobacco enforcement operations for them. The process will involve state enforcement officials using underage buyers to visit retail establishments. The names of those establishments making sales to the underage buyer will be forwarded to the FDA. The FDA will send warning letters or notices of penalty to the retailer (See Appendix 4 for Frequently Asked Questions Concerning FDA Regulations).

As part of a pilot project in 1997, ten states were awarded federal funding to conduct enforcement efforts for the FDA. Additional funding is expected to be available for enforcement in 1998. ABC has made numerous contacts with the FDA concerning the process for applying for funding and the commissioning of agents. ABC's goal was to 'commission' ABC agents to enforce FDA regulations for current agency activities and to develop a contract for future activities. Unfortunately, the FDA has not provided clear guidance concerning the process for obtaining commissions. ABC anticipates applying for federal funding once policy issues concerning the level of activity are clarified.

Proposed Tobacco Settlement Issues

The ensuing tobacco settlement between the federal government and the tobacco industry proposes several actions that have the potential to affect state activities and resources (See Appendix 5 for full text of proposed agreement). The key points of the proposed agreement are as follows:

- **Expanded federal role in tobacco regulation**--FDA role in tobacco regulation is formalized and marketing/advertising restrictions are increased.

- Single State Agency Responsibility--States would have to designate a single state agency to be responsible for all tobacco enforcement activities.

- **Mandatory licensing requirements**--States will be forced to create licensing mechanisms with graduated fines and penalties for violations (34 states currently have tobacco licensing requirements).

- **Specified Enforcement Levels**--Minimum levels of enforcement activity (250 compliance checks per 1,000,000 in population--approximately 1,750 annually).

- **Increased Compliance Targets**--State reporting requirements increased and compliance rate targets are stricter than current Synar targets. After the fifth year of implementation, a 75% compliance rate must be achieved and 90% after ten years. For every one point of deviation, the FDA could withhold one percent of funds otherwise payable to the state to defray the cost of health care programs of medical assistance.

There is a great deal of debate about the proposed settlement. President Clinton has already proposed modifications to the agreement and others have expressed desires for change. While the points listed above have not been discussed publicly, it is unlikely that it will be accepted in its current form. The proposed settlement needs to be monitored closely for possible mandates affecting state resources.

Tobacco Enforcement Activities by the Department of ABC

ABC's Activities to Date

While ABC agents began issuing citations shortly after the passage of HB2530, large-scale enforcement activities did not begin until September 1997. Starting with education, all establishments with alcohol licenses were notified via ABC's newsletter of the changes in law and of ABC's pending activities. A great deal of media coverage throughout the state also helped promote the program. With the approval of its Underage Buyer Program, ABC began using minors to visit establishments selling tobacco products. To date, the Department's efforts have centered on establishments that

failed compliance checks conducted by the Department of Health over the last two years. Through October, 1997, approximately 316 attempts to purchase have been made with 72 being successful. These activities involved at least 20 underage buyers, many of whom participated in numerous compliance checks. Agents devoted approximately 1,550 man-hours to the process but have not yet attended court for the 57 citations to clerks.

Key Policy Issues Affecting Resource Allocation

Desired Level of Activity

The desired level of tobacco enforcement in Virginia is a complex issue involving public policy and resource allocation issues. There is a wide range of activity that is possible for ABC where tobacco law enforcement is concerned. This report will analyze two options: 1) Maintenance of the status quo which for ABC means limiting its activity to the follow-up of Department of Health compliance visits (and any random complaints that may be lodged by citizens), and 2) Full compliance with the proposed settlement agreement which would require ABC to assume the responsibility for all tobacco-related activity including licensing, contracting with FDA for enforcement, reporting, etc.. Implementing either scenario will require an active determination of the desired level of enforcement, clarification of roles of the various state agencies involved, and an allocation of resources.

State Agency Roles

Currently, the responsibility for tobacco enforcement is split between several agencies. DMHMRSAS serves as the contact for Synar compliance reporting. They contract with the DOH for public and merchant education campaigns and the coordination of data collection for Synar reporting purposes. Neither agency has the mechanism or authority to conduct enforcement activities. With the passage of HB2530 and SB1162, ABC became responsible for tobacco law enforcement. As reported earlier, ABC agents are conducting follow-up operations with retailers failing DOH compliance checks. In this phase of the program, ABC is responsible for educating

establishments, recruiting underage buyers, conducting undercover operations, issuing summons for civil violations, testifying in court, and related follow-up analyses and media inquiries.

Opportunities for Process Improvement

The current process is not without confusion. Coordination between agencies is time consuming, prone to error and creates overlapping functions and areas of responsibility. The opportunity exists to improve effectiveness of enforcement efforts and the efficient use of state resources. Many of the functions being performed by DOH on a contract basis are currently being performed by the Department of Alcoholic Beverage Control in the alcohol environment. Centralizing these functions within ABC provides the Commonwealth the opportunity to capitalize on the synergies of combining alcohol and tobacco enforcement. Since the majority of tobacco merchants are already licensed to sell alcohol, significant economies in the education and enforcement arena are available. Centralizing efforts will also make Virginia compliant with the federal requirement as proposed in the tobacco settlement.

Estimates of Manpower Requirements for ABC

Need for Resources Vary Widely

The resources required to implement the scenarios mentioned previously vary widely. They depend on the level of enforcement required, the transfer of responsibility and resources from other agencies, and the level of federal requirements and support. As stated previously, there are two ends of the spectrum. The first is basically the status quo--simple follow-up of Health Department compliance checks and reacting to random complaints by citizens. The second utilizes a more centralized approach as proposed in the tobacco settlement.

Status Quo

By limiting ABC's involvement to the follow-up of DOH compliance checks, no additional resources will be required. As mentioned earlier, the process is less than desirable and

improvements are necessary. More importantly, this relationship will not be in compliance with the proposed tobacco settlement that requires central agency assignment.

Centralized Tobacco Enforcement Program

This scenario assumes that full responsibility for tobacco law enforcement rests with the Department of Alcoholic Beverage Control--including Synar and FDA reporting, compliance checks, licensing, etc.. With the eventual passing of the tobacco settlement, this type of scenario seems to be the more realistic.

ABC currently divides the state into eight geographic regions. Consistent with the tenets of community policing, ABC has broken each region into small territories where agents tend to reside and work. On average, each agent monitors approximately 120 licensed establishments. Adding the responsibility for comprehensive tobacco law enforcement as proposed in the settlement will jeopardize alcohol law enforcement if additional resources are not allocated.

At this point, ABC can only make an educated guess at the impact of adding tobacco law enforcement. Without the licensing requirement, one can only guess about the number of tobacco retailers in Virginia. Based on contacts with the tobacco industry and internal assessments, ABC estimates that there are approximately 13,000 - 15,000 tobacco retailers in Virginia. Based on current sampling, the majority (70% is an optimistic number) are already licensed to sell alcoholic beverages. By adding the non-ABC licensed retailers into the workload, existing agents would have to assume a 30% increase in the number of establishments to monitor. Under this scenario, both tobacco and alcohol law enforcement efforts would be compromised.

ABC estimates that an additional 32 agents (four per region) can handle the additional workload without compromising alcohol law enforcement. The additional number of establishments per agent is nominal under this scenario. The cost of additional agents, program and analytical support, licensing development, public relations campaigns, etc. are expected to be approximately $3.1 million in year one and $2.3 million in subsequent years. A breakdown of the cost

estimates can be found in Appendix 6. Federal funds would be expected to partially offset this expense. Additional resources may also be available through the reallocation of funds currently being allocated to the Department of Health. A nominal license fee could also be used to supplement these expenditures.

Summary of Key Points

Increased Attention on Tobacco at the Federal Level

The enforcement of underage tobacco has received increased attention at the state and federal levels. In Virginia, ABC was allocated the specific responsibility for enforcing the state's underage sales laws. The federal government is also taking an active role through the Synar Amendment and the regulation of tobacco by the FDA. Continued attention is expected as negotiations continue in the tobacco settlement. Many components of this plan create significant requirements for Virginia from both an operational and reporting perspective.

Capitalizing on Opportunities

Many opportunities exist to improve tobacco enforcement in Virginia. Centralizing enforcement and reporting requirements within the Department of Alcoholic Beverage Control creates the opportunity to capitalize on the synergies between alcohol and tobacco law enforcement. This will improve both the efficiency (use of state resources) and effectiveness (reductions in underage sales) of operations. Virginia will also be positioned to capitalize on federal funding opportunities in the near future.

Appendix 1
1997 Virginia Legislation

1997 SESSION

ENROLLED

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 4.1-105 and 18.2-371.2 of the Code of Virginia, relating to enforcement of tobacco laws by special agents of the Alcoholic Beverage Control Board.

[S 1162]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 4.1-105 and 18.2-371.2 of the Code of Virginia are amended and reenacted as follows:

§ 4.1-105. Police power of members, agents and employees of Board.

Members of the Board are vested, and such agents and employees of the Board designated by it shall be vested, with like power to enforce the provisions of *(i)* this title and the criminal laws of the Commonwealth as is vested in the chief law-enforcement officer of a county, city, or town *and (ii) § 18.2-371.2.*

§ 18.2-371.2. Prohibiting purchase or possession of tobacco products by minors or sale of tobacco products to minors.

A. No person shall sell to, distribute to, purchase for or knowingly permit the purchase by any person less than eighteen years of age, knowing or having reason to believe that such person is less than eighteen years of age, any tobacco product, including but not limited to cigarettes and cigars. No tobacco product may be sold from a vending machine (i) except in compliance with subsection E and (ii) unless notice is posted on the machine in a conspicuous manner and place indicating that the purchase or possession of tobacco products by minors is unlawful.

B. No person less than eighteen years of age shall purchase or possess any tobacco product including but not limited to cigarettes and cigars. The provisions of this subsection shall not be applicable to the possession of tobacco products by a person less than eighteen years of age making a delivery of tobacco products in pursuance of his employment.

C. No person shall sell a tobacco product to any individual who does not demonstrate, by producing a driver's license or similar photo identification issued by a government agency, that the individual is at least eighteen years of age. Such identification is not required from an individual whom the person has reason to believe is at least eighteen years of age or whom the person knows is at least eighteen years of age. Proof that the person demanded, was shown, and reasonably relied upon a photo identification stating that the individual was at least eighteen years of age shall be a defense to any action brought under this subsection. In determining whether a person had reason to believe an individual is at least eighteen years of age, the trier of fact may consider, but is not limited to, proof of the general appearance, facial characteristics, behavior and manner of the individual.

This subsection shall not apply to mail order sales.

D. A violation of subsection A, ~~B,~~ or C by an individual or by a separate retail establishment shall be punishable by a civil penalty not to exceed ~~fifty dollars~~ *$100* for a first violation and a civil penalty not to exceed ~~$100~~ *$200* for a second violation. However, a third or subsequent violation of subsection A shall be punishable by a civil penalty not to exceed ~~$250~~ *$500*. ~~A third or subsequent violation of subsection B shall be punishable by a civil penalty not to exceed $100, and~~ *A violation of subsection B shall be punishable by a civil penalty not to exceed $50 for a first violation and a civil penalty not to exceed $100 for a second or subsequent violation. Upon a third or subsequent violation of subsection B,* the judge in his discretion may enter an order pursuant to subdivision 9 of § 16.1-278.8. Any attorney for the Commonwealth of the county or city in which an alleged violation occurred may bring an action to recover the civil penalty, which shall be paid into the state treasury. Any law-enforcement officer may issue a summons for a violation of subsection A, B, or C.

E. 1. Cigarettes shall be sold only in sealed packages provided by the manufacturer, with the required health warning. The proprietor of every retail establishment which offers for sale any tobacco product, including but not limited to cigarettes and cigars, shall post in a conspicuous manner and place a sign or signs indicating that the sale of tobacco products to any person under eighteen years of age is prohibited by law. Any attorney for the county, city or town in which an alleged violation of this subsection occurred may enforce this subsection by civil action to recover a civil penalty not

to exceed fifty dollars. The civil penalty shall be paid into the local treasury. No filing fee or other fee or cost shall be charged to the county, city or town which instituted the action.

2. No person shall operate a vending machine which dispenses tobacco products unless such a machine is located in:

a. A place that is not open to the general public and is not generally accessible to minors; or

b. A place that is open to the general public. Such a vending machine shall be inside the establishment and unless the vending machine is at least ten feet from any public entrance to the establishment, or the sale of a token is required to operate such a machine, it shall be placed within the normal unobstructed line of sight of the proprietor or his employees.

3. For the purpose of compliance with regulations of the Substance Abuse and Mental Health Services Administration published at 61 Federal Register 1492, the Department of Agriculture and Consumer Services may promulgate regulations which allow the Department to undertake the activities necessary to comply with such regulations.

4. Any attorney for the county, city or town in which an alleged violation of this subsection occurred may enforce this subsection by civil action to recover a civil penalty not to exceed $100. The civil penalty shall be paid into the local treasury. No filing fee or other fee or cost shall be charged to the county, city or town which instituted the action.

F. Nothing in this section shall be construed to create a private cause of action.

G. Agents of the Virginia Alcoholic Beverage Control Board designated pursuant to § 4.1-105 may issue a summons for any violation of this section.

2. That the Virginia Alcoholic Beverage Control Board shall report any additional fiscal and manpower needs necessary to comply with the provisions of this section to the Governor and the General Assembly in December 1997 and December 1998.

Appendix 2
Synar Amendment Information

Prevention Pipeline

Drug Free Communities by the Year 2000

March/April 1997

Preventing Tobacco Use Among Youth

States Receive Assistance With Synar Regulation Requirements

by Deborah Fisher, PhD, and Maria Carmona

After years of little progress in reducing tobacco use among teens, the Federal Government's recently implemented Synar Regulation offers States a new challenge and a useful tool in the fight to reduce tobacco sales to minors. Although it is illegal in every State for individuals under 18 years of age to purchase tobacco, minors have had easy access to tobacco products because the laws rarely have been enforced. Every day in the United States, 3,000 children and adolescents become regular smokers; this translates to more than one million new underage smokers per year. One in three of these young people who continue to smoke in adulthood will die of a smoking-related disease. In an effort to delay the initiation and reduce the continued use of tobacco by youth through restricting access, Congress passed the Synar Amendment, named for its sponsor, the late Congressman Mike Synar of Oklahoma. The goal is to reduce the rate of illegal purchases by minors to no more than 20 percent in each State. Reducing sales of tobacco to minors through the Synar Regulation will reduce both current and future health problems among adolescents and is consistent with the public's support of measures to prevent the use of tobacco by young people.

In order to assist States and territories in implementing the Synar Regulation, the Center for Substance Abuse Prevention (CSAP) recently hosted a technical assistance workshop in Crystal City, VA. Three documents prepared by the National Center for the Advancement of Prevention (NCAP) were released at the workshop and are now available.

Features of the Synar Regulation
Requires States to enact and enforce laws prohibiting any manufacturer, retailer, or distributor from selling or distributing tobacco products to minors
Requires States to conduct random, unannounced, annual inspections of a sample of tobacco vendors to assess their compliance with the State's access law.
Requires States to submit an annual report to the Secretary of Health and Human Services describing their enforcement activities, their progress in reducing access, and a strategy and timeframe for achieving a noncompliance rate of 20 percent or less.
Allows for a percentage of Federal block grant funds for substance abuse prevention to be withheld from noncompliant States.

Workshop presenters included State administrators, local government officials, law enforcement officials, researchers, media professionals, and community advocates. During the 2-day course of presentations, workshop participants learned how communities and States have addressed a variety of obstacles in their youth-focused tobacco control efforts. A few of the lessons learned from their experiences follow.

- Frame the issue in a positive light. Describing the State of Kansas' recent passage of youth access legislation, Julia Francisco from the State's Department of Health and Human Services noted how the legislation was ushered in through a legislative committee concerned with child welfare. Care should be taken to ensure that youth access legislation is viewed as beneficial to both individuals and society at large.

- Keep focused on health and don't get distracted by other issues. Dr. Donna Bacchi of the Austin-Travis County Department of Health and Human Services spoke of how an effort to pass a series of local ordinances encountered opposition from residents and businesses who raised questions about individual rights and undue burdens on tobacco retailers. She advised that maintaining youth access legislation as a public health issue forces opponents into a difficult position of seeming to advocate for illness and danger.

- Don't let your guard down! Biddy Bostick from West Virginia's Division on Alcoholism and Drug Abuse recalled how tobacco proponents attached a preemption clause to mining legislation that was all but certain to pass during one evening legislative session. Preemption would have prohibited communities from enacting stricter youth access ordinances at the local level. Thanks to the watchful eye of one coalition member, tobacco control advocates were able to lobby State legislators into striking the preemption clause from the legislation.

- Work in partnership with merchants. Shirley Angiulo, who coordinates the Tobacco Compliance Check Program for the Akron Health Department, noted that you can catch more flies with honey than with vinegar. She describes her task to merchants as one that involves assisting them in complying with the law. She also regularly solicits advice from merchants about how education efforts can be made more effective.

- Personal contact with violators is extremely effective. Angiulo's program requires violators (salesclerks and store owners) to appear before Department officials and to participate in an offsite merchant education program. She said that subsequent compliance checks indicate that this personal contact is extremely effective in reducing sales to minors.

- Use positive reinforcement, as well as penalties, to encourage compliance. Psychologist Anthony Biglan provided research evidence that positive reinforcement and incentives for complying with the law can be effective. When compliant merchants were recognized through public expressions of thanks (e.g., newspaper notices), the free and positive publicity afforded their businesses caused them to remain vigilant when making subsequent tobacco sales.

- Start with an inside supporter. Another researcher, Ellen Feighery, suggested that efforts to prompt active enforcement of youth access laws (often not a high priority) may be more successful if they start by identifying and engaging an individual within the enforcement agency who is already on board the youth access issue. Working with this inside supporter, proponents may gain entree to and greater attention from other law enforcement officials, as well as valuable assistance in building a strong case for enforcement.

- Involve local law enforcement agencies. Involving local law enforcement agencies in efforts to enforce the State's youth access law can help reduce the challenges faced by State-led enforcement programs, such as insufficient funding and personnel resources, large geographic areas, and diverse populations. Senior Deputy Attorney General John Albrecht spoke about how the Office of the Attorney General in Nevada has effectively contracted with local police and sheriffs' departments to conduct the retail outlet inspections required annually by Synar.

- Use DARE and community police officers in enforcement activities. Sergeant Steve Moran of the Bensalem, PA, police department explained how tobacco control efforts in his community have adopted a community policing model that includes strong cooperation between the police and parent-teacher organizations. DARE officers have provided technical assistance, obtained financial support through grant writing, trained minors to conduct compliance checks, and conducted inspections with youth. To the extent that DARE and community police officers can perform these functions as part of their existing positions, more aggressive enforcement can be undertaken without added expense to local law enforcement agencies.

- Seek opportunities for collaboration. Joy Rockenbach of the Arkansas Department of Health suggested that before establishing a new coalition, citizens should find out whether any existing advocacy and community groups are already working on other tobacco and health-related issues. For example, the Federal Government (through ASSIST and IMPACT programs) and private foundations fund tobacco control initiatives in each State. It may be easier and more efficient to pursue restrictions on youth access to tobacco with a coalition that has been active in the community and already has resources, contacts, and experience.

- Involve youth in getting the message out. Rebecca Murphy of the Utah Department of Health spoke about the benefits of involving youth in media efforts. Young people can provide valuable input on the design and creation of media campaigns that target youth with their messages. In addition, young people can serve as effective spokespersons on the issue of youth access. Press events that feature youth attract media attention and coverage. Don't overlook youth as valuable resources!

Three Guidance Documents On Implementing Synar

Sample Design Guidance provides information about sampling design issues and offers 10 guidelines to assist State agencies in meeting the requirements of the regulation. The document enables States to employ survey sampling procedures based on accepted statistical theory, in spite of the challenges that might be posed by geography and other contextual issues.

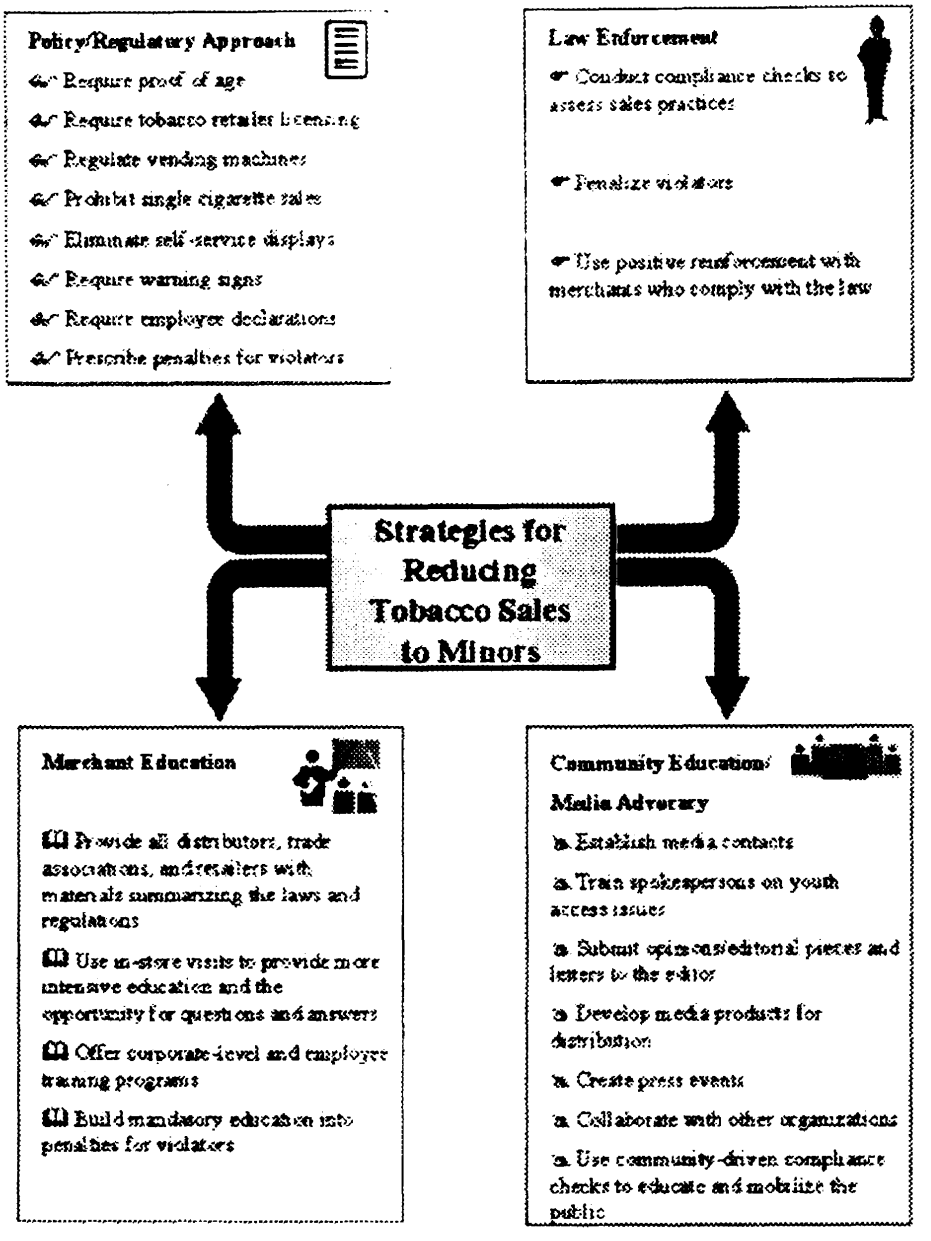
Tobacco Outlet Inspection Guidance presents information on methods for performing inspections of tobacco retail outlets as required by the law. It suggests standardized procedures and protocols for inspections so that measurements are comparable across all jurisdictions within States, over time, and, ideally, among States.

Strategies for Reducing Sales of Tobacco Products to Minors provides information about important issues and tested strategies for reducing sales to minors. It summarizes key data on tobacco use by adolescents, health consequences of tobacco use, and tobacco sales to minors. The document also describes specific strategies for reducing sales to minors in four general areas: laws and policies, law enforcement, merchant education, and community education and media advocacy. It concludes with case studies of actual intervention efforts that may assist States and communities in developing their own interventions to reduce the rate of underage tobacco sales.

Reducing the rate of tobacco sales to minors is an important step in reducing the overall rate of tobacco use among Americans. Studies show that most adult consumers of tobacco products began using tobacco products as children or adolescents. If the Nation can succeed in reducing the number of children and adolescents who become regular smokers before the age of 18, it will significantly reduce the number of regular adult smokers of the future. It will also have saved countless persons from suffering myriad tobacco-related illnesses and death and saved American taxpayers from shouldering related medical care costs of over $21 billion per year.

For more information about the facts on underage tobacco sales and use or to receive a copy of Strategies for Reducing Sales of Tobacco Products to Minors, please contact the Division of Science Dissemination at NCAP (301) 984-6500.

Deborah Fisher, PhD, is senior project manager and Maria Carmona is senior project manager at the National Center for the Advancement of Prevention in Rockville, MD.



A Giant Leap Forward In Tobacco Control

President Clinton took a bold step last fall to prevent tobacco use by American youths. After concluding that tobacco does in fact come under the domain of the Food and Drug Administration (FDA), President Clinton announced several new rules aimed at preventing the sale and advertising of cigarettes and smokeless tobacco to youth. Currently, 3 million adolescents smoke cigarettes, 1 million use smokeless tobacco, and another 1 million young people become regular smokers each year. One out of every 3 kids will die prematurely as a result of their tobacco use habit.

The President's goal to -- cut tobacco use by adolescents in half over the next 7 years -- is a significant prevention initiative to reduce the 400,000 deaths attributed to tobacco use each year.

"This is the most important public health initiative of our generation," said Health and Human Services Secretary Donna E. Shalala when the new rules were announced. "Our children's futures are at stake. President Clinton's action will ensure that children get their information about tobacco from their parents -- and not from Joe Camel."

A growing body of evidence showing that cigarettes and smokeless tobacco products deliver a pharmacologically active dose of nicotine to the body and have potentially dangerous effects prompted the FDA's assertion that tobacco products fall under its control. In addition, new research on the addictive nature of nicotine and how tobacco companies manipulated the nicotine levels in their products further supported the FDA's contention that cigarettes and smokeless tobacco fall under its domain because they contain a drug that causes addiction -- nicotine -- and because cigarettes and smokeless tobacco products are devices for delivering nicotine to the body.

While the FDA could conceivably ban the sale of all tobacco products, regardless of the smoker's age, it has chosen to break the cycle of addiction by preventing children from starting the habit.

"We have to tell our children the truth about the diseases caused by smoking," said FDA Commissioner David A. Kessler, MD. "For too long we have sent conflicting messages to our children and then have acted surprised when they begin to smoke."

Studies suggest that anyone who does not begin to use tobacco as a child or adolescent is unlikely to start as an adult. Eighty-two percent of adults who ever smoked had their first cigarette before age 18, and more than half of them had already become regular smokers by that age. A study by John Pierce, PhD, and Elizabeth Gilpin, of the University of California, San Diego, concluded that teenage boys who start smoking now will smoke for at least 16 years; girls will smoke for at least 20 years. The researchers recommend that "efforts to prevent experimentation must be given a high priority" (American Journal of Public Health, Vol. 86 No. 2, February 1996).

The FDA rules focus on two strategies for tobacco control: access and advertising. Under the access portion the rules say:

- The sale of cigarettes and smokeless tobacco to anyone younger than 18 is illegal;
- Retailers must verify that purchasers are 18 or older by checking identification that includes the bearer's date of birth and photograph; and
- Retailers must check identification of anyone 26 or younger.

Retailers are also prohibited from opening any cigarette packet or smokeless tobacco product to sell or distribute individual cigarettes or smaller amounts of tobacco. Free samples are banned. Twenty cigarettes is the minimum package size, which ends the sale of small, easy to conceal, so-called "kiddy" packets.

Vending machines selling tobacco products are banned except in those limited locations in which the retailer or operator can ensure that no person younger than 18 is present or permitted to enter at any time (such as a nightclub). The FDA will monitor compliance with the vending machine rule for 2 years and will propose additional restrictions if there is evidence that young people are continuing to purchase tobacco products from these machines.

Self-service displays of tobacco products are banned as well as mail order redemption of coupons for free cigarettes or discounted cigarettes. Mail order sales will be monitored by FDA to ensure that they do not

Date: Thursday, Jan. 18, 1996
FOR IMMEDIATE RELEASE
Contact: Victor Zonana (202) 690-6343

HHS AND SAMHSA ISSUE FINAL RULE ON YOUTH ACCESS TO TOBACCO

The Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) today issued a final rule designed to ensure that states and territories adopt and enforce laws prohibiting the sale or distribution of tobacco products to children.

The rule provides guidance to the states on how to comply with the Synar Amendment, named for its author, the late Mike Synar, former Congressman from Oklahoma. Synar died of brain cancer Jan. 9. The amendment was enacted in 1992 as part of the Public Health Service Act and requires states to have and to enforce laws banning the sale and distribution of tobacco products to people under 18.

While all states currently have such laws, enforcement has been inconsistent; in 1991, an estimated 255 million cigarette packs were sold illegally to minors, according to the American Journal of Public Health. And in the 1995 Monitoring the Future Survey released last month, more than 90 percent of high school tenth graders surveyed said it was "fairly easy" or "very easy" to obtain cigarettes.

"The Synar regulation is an important part of the Clinton Administration's overall effort to help parents protect their children from the dangers of tobacco," said HHS Secretary Donna E. Shalala.

On August 10, President Clinton announced proposals by the Food and Drug Administration (FDA), another HHS agency, designed to reduce the access and appeal of tobacco products to young people. The FDA is currently reviewing public comments it received on its proposed regulations.

"These two initiatives would complement one another, and are intended to limit the access and appeal of tobacco products to young people," Shalala said.

Together, Shalala said, the Synar regulation and the proposed FDA regulations would provide a means to achieve President Clinton's goal of reducing the use of tobacco products by young people 50 percent within seven years.

The Synar regulation -- formally titled "Substance Abuse Prevention and Treatment Block Grants: Sale or Distribution of Tobacco Products to Individuals Under 18 Years of Age" -- requires states and territories to enforce their youth access laws through such methods as random spot checks of retail establishments. It would also require states to designate an office or agency for coordinating compliance activities.

States would be required to file annual progress reports and could suffer financial penalties through reductions in substance-abuse block grants for failing to achieve agreed-upon goals.

"States should have broad flexibility in achieving our common goal of preventing youth addiction to tobacco products, but we have to have effective enforcement," Nelba Chavez, SAMHSA's administrator, said.

"Despite the existence of laws barring the sale of tobacco to minors in all 50 states, enforcement has been uneven," Chavez continued.

provide young people with a mechanism for purchasing tobacco products.

Within the advertising portion, FDA prohibited outdoor advertising within 1,000 feet of public playgrounds, elementary schools, or secondary schools. Tobacco advertising in all existing media forms must be in a black and white, text only format except in publications read primarily by adults and adult-only locations.

Tobacco companies will not be allowed to sell or distribute promotional items such as T-shirts, caps, and sporting goods identified with tobacco products. Sporting and entertainment events cannot be sponsored by a brand of tobacco but they can be sponsored under the corporate name.

FDA is also requiring six major tobacco manufacturers to establish and fund a national public education program to inform adolescents about the dangers of smoking.

These provisions will be phased in to allow businesses adequate time to comply.

In response to FDA's rules, the four largest tobacco companies filed a motion in the U.S. District Court for Central North Carolina for a summary judgment against the FDA. Philip Morris Cos., the Brown & Williamson unit of BAT Industries, RJR Nabisco Holdings Corp.'s RJ Reynolds Tobacco Co., and Loews Corp.'s Lorillard Tobacco, Inc., contend that FDA does not have jurisdiction over tobacco, while advertising agencies such as Coyne Beam, Inc., contend that advertising restrictions violate free speech guarantees.

Tobacco-growing States are also concerned about the impact these rules will have on their economy. North Carolina's Governor Jim Hunt sent a letter to the FDA predicting that the new regulations would devastate North Carolina -- a State where tobacco provides 260,000 jobs and generates over $5.5 billion to those workers. If implemented, the rules would cost North Carolina $73 million annually. In the Charlotte Observer (January 7, 1996) U.S. Representative Richard Burr (R-NC) stated that President Clinton "could have worked with members of Congress, parents and the tobacco industry, who have already offered legitimate proposals to implement a plan curbing minors' access to tobacco products." But instead, asserted Burr, the President chose to "grant the FDA increased authority to regulate tobacco knowing full well that the issue would wind up in court." Virginia and Kentucky are also supporting the tobacco industry's court challenge to the FDA rules.

In their own attempts to control youth access to tobacco, Philip Morris, RJR Reynolds, and the Tobacco Institute -- an industry trade group -- each sponsor programs to encourage merchant compliance with laws prohibiting sale of tobacco to minors by distributing education materials and stickers to the stores. These programs are collectively referred to as "It's the Law" programs.

However, a study by Joseph DiFranza, MD, and his colleagues at the Department of Family and Community Medicine, University of Massachusetts Medical Center, on youth access to tobacco via over-the-counter sales and vending machines (locked and unlocked) found that these programs "were not associated with a significant reduction in illegal sales either when vending machines and over-the-counter sources were considered together or separately." Of the 480 attempts by 14 to 15 year olds in the State of Massachusetts to buy cigarettes, 33 percent were successful (American Journal of Public Health, Vol. 86, No. 2 February 1996).

"Moreover," added Shalala, "the problem of teen smoking is getting worse."

Last month, the 1995 Monitoring the Future Survey reported continued large increases in smoking among 8th, 10th and 12th graders.

Among 10th graders, 27.9 percent had smoked within 30 days of the survey, up from 25.4 percent a year earlier, and 16.3 percent smoked every day, compared to 14.6 percent a year earlier.

Among 12th graders, fully 33.5 percent had smoked within 30 days of the survey, up from 31.2 percent in 1994. Daily smoking among 12th graders increased to 21.6 percent from 19.4 percent.

And among the youngest members of the survey -- eighth graders who may be as young as 13 -- daily cigarette use jumped to 9.3 percent in 1995 from 7.2 percent in 1991, while past-month smoking among eighth graders soared to 19.1 percent from 14.3 percent in 1991.

"This four-year trend of increased smoking among American youth, if not reversed, will cost this country thousands of precious lives and billions of dollars in health costs," Shalala warned.

Shalala pointed to another worrisome finding in the Monitoring the Future survey. "Over 90 percent of tenth graders and 76 percent of eighth graders said it was fairly or very easy to get cigarettes," she said.

About 3,000 young people under the age of 18 become regular smokers every day and nearly 1,000 of them will eventually die of tobacco-related illnesses.

Appendix 3
FDA Regulations and Legal Issues

U.S. Food and Drug Administration

Executive Summary

The Regulations Restricting the Sale and Distribution Of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

I. Introduction

With the August 1996 publication of a final rule on tobacco in the *Federal Register*, the Food and Drug Administration (FDA) will regulate the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. The action results from the agency's assertion of jurisdiction over tobacco products. This was based on an intensive FDA investigation of the tobacco industry, tobacco use and its health consequences. The rule will prohibit the sale of cigarettes and smokeless tobacco to those under 18 while leaving them on the market for adults.

Tobacco use is the single leading preventable cause of death in the United States.[1] It kills more than 400,000 Americans each year [2] -- more people each year than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined.[3]

The use of tobacco products, and the resulting nicotine addiction, begins predominantly in children and adolescents and is, consequently, a pediatric disease. Approximately 3 million American adolescents currently smoke, and an additional 1 million adolescent males use smokeless tobacco.[4] Each year, another 1 million young people become regular smokers.[5] Approximately one out of every three of these young people will die prematurely as a result.[6]

Studies suggest that anyone who does not begin to use tobacco as a child or adolescent is unlikely to start as an adult. Eighty-two percent of adults who ever smoked had their first cigarette before age 18, and more than half of them had already become regular smokers by that age.[7] Among smokers ages 12 to 17 years, 70 percent already regret their decision to smoke and 66 percent say that they want to quit.[8]

Furthermore, studies show that children and adolescents are starting to smoke at earlier and earlier ages.[9] Data reported in December 1995 showed that the proportion of 8th- and 10th-graders who reported smoking in the 30 days before the survey had risen by one-third since 1991, to about 19 percent and 28 percent respectively.[10]

Similar problems exist with underage use of smokeless tobacco. School-based surveys in 1991 estimated

that 19.2 percent of 9th- to 12th-grade boys use smokeless tobacco.[11]

Finally, studies show that young people do not fully understand the serious health risks of these products, or believe that those risks do not apply to them. They are also very impressionable and therefore vulnerable to the sophisticated marketing techniques employed by the tobacco industry, techniques that associate the use of tobacco products with excitement, glamour, and independence.

The wealth of information assembled by the agency about nicotine's addictive properties led FDA to conclude that it has jurisdiction over tobacco products. The age of onset of nicotine addiction, and its well-known consequences, suggested the best way for the agency to regulate tobacco to protect the public health.

Of the fifty million12 people who smoke cigarettes, 77-92 percent are addicted.[13] Because an outright ban of tobacco products could have profound health consequences for these tens of millions of addicted smokers, FDA has chosen instead to focus on preventing children and adolescents from becoming addicted to these products in the first place. Evidence in the administrative record (the collection of documents gathered by FDA during its investigation and made publicly available) demonstrates that the most effective way to achieve this goal is to limit the access to, and appeal of, cigarettes and smokeless tobacco to children and adolescents.

Specifically, the rule makes the sale of cigarettes and smokeless tobacco to children and adolescents, anyone younger than 18 years of age, a federal violation. In addition, the rule requires manufacturers, distributors, and retailers to comply with certain conditions regarding the sale, distribution and promotion of tobacco products. It prohibits all free samples and limits retail sales in most circumstances to face-to-face transactions. As a result, vending machines and self-service displays are prohibited, except in facilities where the retailer or operator ensures that no person younger than 18 is present or is permitted to enter at any time.

The rule limits advertising generally to a black-and-white, text-only format to ensure that advertising is not used to create demand for these products among young people and thus undermine the restrictions on access. Billboards and other outdoor advertising are prohibited within 1,000 feet of schools and public playgrounds. The sale and distribution of non-tobacco items, such as hats and tee shirts that carry cigarette logos, such as Joe Camel, are prohibited, and sponsorship of sporting and other events is limited to the corporate name only.

II. Background

The Food and Drug Administration proposed to regulate tobacco products on August 10, 1995. This proposed rule, which was published in the *Federal Register* on August 11, resulted from a more than yearlong investigation by FDA into the role that nicotine plays in tobacco products, patterns of tobacco product use, and the role of advertising and promotional practices in young people's decision to use tobacco products.

From publication of the proposed rule in August 1995 until January 1996, FDA accepted comments from the public. Reactions came from many sections of society, including the tobacco and advertising industries, medical and public interest groups, and individual citizens. FDA reopened the comment period for one month from mid-March to mid-April to accept public comments on specific documents that were

added to the public record.

The agency received more comments on the proposed rule -- some 700,000 pieces of mail -- than at any other time in the history of federal rule making. Both supporters and opponents organized campaigns to generate reactions to the proposed rule; the agency identified more than 500 different types of form letters. One massive campaign, which opposed the rule, generated over 300,000 pieces of mail -- 42 percent of all the mail received. Some 95,000 people, including more than 35,000 children, sent individual views. The children's comments were overwhelmingly supportive. The largest single comment, submitted by the cigarette industry, consisted of approximately 45,000 pages.

Although many of the comments were addressed to specific provisions of the proposed regulation, tens of thousands of letters contained general comments. Many expressed strong overall opposition to the rule; many others expressed strong support. Comments came from every corner of the country, from federal, state and local government officials, from smokers who felt the government was inappropriately meddling in their lives, and from smokers desperate, but unable, to quit. The agency heard from employers and employees in the affected industries, including tobacco farmers, wholesalers, cigarette manufacturers, and laborers who fear that the regulation may cause the loss of their employment. One supportive letter came from a coalition of medical associations representing 125 groups with more than 18 million members. Supporters and opponents alike agreed that children under age 18 should not use nicotine-containing tobacco products.

Some comments opposing the proposed rule argued that FDA should not regulate tobacco and should focus instead on its traditional responsibilities. Still others said FDA should not interfere with the free choice of adults, and some feared that the rule was just the first step toward a total ban. Additional comments opposing the proposed rule in general argued that there is no need to regulate tobacco because the products are already highly controlled.

In contrast, comments supporting the proposed rule said that existing tobacco regulations do not address the health consequences of tobacco, nor do they effectively prevent sales to minors. Many pointed out that tobacco use is the single most preventable cause of death in the United States, and that, because of the serious health risks associated with these products, it is essential that the government take action to reduce the number of young people who begin smoking or using smokeless tobacco. A number of comments indicated that children and adolescents are drawn to the images associated with smoking and that steps should be taken to prevent young people from being bombarded by these tobacco messages.

III. Overview of Statutory and Constitutional Authority

The federal Food and Drug Administration's authority to carry out its mission to protect the public health derives primarily from the federal Food, Drug, and Cosmetic Act (the act).[14] This statute provides the agency authority to regulate a wide array of consumer products, including drugs and devices.

In order to assert jurisdiction over cigarettes and smokeless tobacco, these products must meet at least one of the definitions of a regulated product. As discussed thoroughly in the 1996 Jurisdictional Determination,[15] FDA has concluded: (1) that cigarettes are "combination products," having both a drug component, including nicotine, and device components, namely processed tobacco, the ventilation system, and filters; and (2) that smokeless tobacco is a combination product that consists of a drug component, nicotine, and device components, specifically processed tobacco, and for some products, a

porous pouch.

Congress gave the agency considerable latitude to decide whether to regulate drug/device combination products using the act's drug authorities, device authorities, or both. FDA has determined that tobacco products are most appropriately regulated under the device provisions of the act, including the restricted device authority in section 520(e) of the act, which allows the agency to impose restrictions on the sale, distribution, and use of a product.

During the public comment period, some opponents challenged FDA's legal authority to impose the proposed restrictions, arguing that the agency's action would violate various laws and parts of the Constitution, including the Separation of Powers and Nondelegation doctrines, and the First, Fifth, Ninth and Tenth Amendments. After carefully considering these arguments, the agency has concluded that the statutory and constitutional bases of FDA's jurisdiction and regulation are sound.

IV. The Rule

The provisions of the rule are based on the agency's investigation of tobacco products and nicotine's addictiveness, the evidence in the public administrative record, and the review and consideration of the comments received on the proposed rule. In some instances, that review strengthened FDA's original position; in others, it caused the agency to either eliminate or modify some provisions.

1. Restricting Access to Children and Adolescents

The rule makes the sale of cigarettes and smokeless tobacco products to children and adolescents younger than age 18 a violation of federal law. Currently, young people purchase an estimated $1.26 billion of tobacco products annually. [16] Despite laws in all 50 states that prohibit sales to minors, numerous studies show that adolescents have little difficulty purchasing tobacco products. The 1994 Surgeon General's report examined 13 studies of over-the-counter sales and determined that approximately 67 percent of minors were able to purchase cigarettes illegally.[17] Significant numbers of young people successfully purchase smokeless tobacco as well, with 90 percent of smokeless tobacco users in junior high and high school saying they buy their own smokeless tobacco.[18]

Other studies indicate that actively enforced access restrictions have been effective. For example, a comprehensive community intervention in Woodridge, Illinois, involving retailer licensing, regular compliance checks, and penalties for merchant violations, reduced illegal sales from 70 percent to less than five percent in under two years.[19] Rates of both experimentation and regular smoking decreased more than 50 percent among seventh and eighth grade students in this community.

This study, as well as other studies reviewed by FDA, led the agency to draft a comprehensive proposal to reduce young people's access to cigarettes and smokeless tobacco, and to make explicit the responsibility of manufacturers, distributors, and retailers to prevent cigarette and smokeless tobacco product sales to persons under 18 years of age. The access portion of the rule has several major provisions, including:

a. Minimum Age

The regulation prohibits retailers from selling cigarettes and smokeless tobacco to anyone younger than 18 years of age. Retailers must verify that purchasers are 18 or older by checking identification that includes the bearer's date of birth and photograph The rule requires retailers to check the identification of anyone 26 or younger. Acceptable identification could include a driver's license or college identification card.

The need for this provision is supported by studies indicating that minors who purchase cigarettes and smokeless tobacco from stores are rarely asked for identification. One study found that 67 percent of teenagers, whose mean age was 15 years, were asked no questions when they attempted to purchase cigarettes.[20]

b. Minimum Package Size

Under the rule, retailers are prohibited from opening any cigarette package or smokeless tobacco product to sell or distribute individual cigarettes or smaller amounts of tobacco. [21] In addition, the regulation establishes 20 cigarettes as the minimum package size. Both provisions are designed to prevent the kind of sales that are attractive to young smokers -- small, inexpensive, easy to conceal "kiddie" packs.

Although kiddie packs have only recently begun appearing in the United States, studies in countries where they have been available show that kiddie packs are preferred by adolescents far more than by adults. For example, one study in Australia showed that 56.3 percent of all 14 to 15 year old smokers had purchased kiddie packs in the month prior to the survey, compared with only 8.8 percent of adult smokers.[22]

c. Vending Machines

The rule bans the use of vending machines in almost all circumstances. Vending machines represent one of the major ways that children currently obtain cigarettes. Numerous studies and surveys show that significant percentages of young people are able to purchase cigarettes from vending machines, even in areas that have laws restricting the placement of those machines or requiring the use of locking devices.

The 1994 Surgeon General's Report examined nine studies of vending machine sales and found that children and adolescents successfully purchased cigarettes from vending machines 88 percent of the time.[23] In addition to studies demonstrating how easily children can purchase cigarettes from vending machines, the proposed rule cited surveys of children's actual purchasing behavior. Vending machines are most popular with the youngest smokers, with 22 percent of 13 year olds who smoke purchasing cigarettes from them compared with 2 percent of 17 year olds.[24]

The provision to eliminate the use of vending machines generated numerous comments. Comments in opposition argued that the provision would be unnecessary if state and local governments enforced existing laws prohibiting the sale of tobacco products to children under the age of 18. They also argued that most vending machines are located in areas that are off-limits to children, such as night clubs or casinos, or in areas that children rarely frequent, such as industrial plants and private offices.

Conversely, nearly all comments in favor of the provision argued that vending machines, including those in "adult-only" locations and those with locking devices, offer children easy access to tobacco products. Tens of thousands of school children wrote letters asking that vending machines be eliminated.

FDA has decided that cigarettes and smokeless tobacco should not be sold from vending machines except

in those limited locations in which the retailer or operator ensures that no person younger than 18 is present or permitted to enter at any time. This exception to the ban on vending machines is intended to be narrow and carefully circumscribed.

While the agency agrees that some children who are determined to use cigarettes or smokeless tobacco may find or create new ways of obtaining them, FDA has concluded that the removal of vending machines from sites accessible to young people will eliminate what is currently a popular and easy means of access to tobacco, especially for younger children In addition, if other access restrictions are imposed, such as requiring customers to provide proof of age, without also eliminating vending machines, use of vending machines among children and adolescents would likely increase. Therefore, the agency has concluded that the provision is an important part of the overall effort to reduce children's access to cigarettes and smokeless tobacco.

FDA will monitor compliance with the provisions governing vending machines for two years and will propose additional restrictions if there is evidence at that time that young people are continuing to purchase tobacco products from these machines.

d. Self-Service Displays

The rule also bans the use of self-service displays of tobacco products, with certain exceptions,[25] to prevent young people from helping themselves to these products. This will reduce the likelihood of theft and increase the involvement of sales clerks in transactions with young people. Self-service displays permit children and adolescents to quickly, easily, and independently obtain cigarettes and smokeless tobacco. A study by the National Academy of Sciences' Institute of Medicine found that over 40 percent of grade school students who smoked daily shoplifted cigarettes, at some time, from self-service displays.[26] One study found that tobacco sales to minors dropped 40 to 80 percent after enactment of ordinances prohibiting self-service displays and requiring vendor-assisted sales.[27] In addition, the Institute of Medicine reported that placing products out of reach "reinforces the message that tobacco products are not in the same class as candy or potato chips." [28]

e. Mail Order Sales and Redemption of Coupons

The proposed rule would have prohibited the use of mail-order sales and mail-order redemption of coupons because there is no reliable way to verify the consumer's age. At the time FDA issued the proposed rule, the standard industry practice simply required the consumer to provide a birth date or check a box to signify that he or she was of legal age.

The agency received many comments on this provision. Opponents argued that young people do not buy cigarettes through the mail because they do not have checks or credit cards with which to pay for them. Many adults stated that they prefer mail-order sales because the products are unavailable in stores or are less expensive. Others said mail order sales serve those in rural or isolated areas, and that the rule would eliminate the principal or sole source of tobacco for those adults.

After reviewing the comments, FDA decided to allow mail order sales of tobacco products. There is little or no evidence to show that young people use mail order sales to any significant degree. However, the agency is concerned that children and adolescents may turn to mail order sales if access to tobacco products is denied in other ways. Therefore, FDA will monitor mail order sales to ensure that they do not provide young people with a mechanism for purchasing cigarettes and smokeless tobacco.

Mail-order redemption of coupons for free cigarettes or discounted cigarettes will not be permitted on the basis that the agency did receive evidence that young people were able to obtain free samples in this manner. Evidence from the attorney general of Massachusetts showed that as part of an operation conducted by his office, 30 young people mailed in coupons for free samples of smokeless tobacco. Virtually all of them received their free samples in the mail.[29]

Contrary to the concerns expressed by a number of adults, this provision does not prevent adults from receiving coupons through the mail as long as they redeem the coupons in person where a sales clerk can verify the customer's age.

f. Free Samples

The regulation prohibits the distribution of free samples of cigarettes or smokeless tobacco. Free samples are often distributed at "mass intercept locations," such as street corners and shopping malls, and at events such as festivals and concerts. Free samples represent a "risk-free" and "cost-free" way for young people to obtain cigarettes or smokeless tobacco. Surveys and reports demonstrate that young people can obtain free samples easily in spite of voluntary industry codes. For example, one survey in New Jersey found that one-third of approximately 500 high school students who were current or former smokers reported receiving free cigarette samples before the age of 16.[30]

A few comments opposed any restrictions on free samples, claiming that eliminating free samples would violate the rights of adult consumers, reduce choices for adults, or deprive adults of an opportunity to save money. In contrast, many comments, including several that opposed the remainder of the rule, supported a ban on free samples. Comments cited instances where young people easily obtained free samples of cigarettes and smokeless tobacco.

While the ban on free samples will affect adults, no suggestions were made on how to prevent free samples from reaching young people. The agency determined that the benefits gained from eliminating free samples for young people outweigh any inconvenience to adults.

2. Reducing Appeal of Advertising to Children and Adolescents

In August 1995, FDA announced its proposal to restrict cigarette and smokeless tobacco advertising in ways that would reduce the appeal of such ads to children and adolescents. FDA's purpose in proposing the advertising restrictions was to ensure that the access restrictions are not undermined by advertising that heightens the appeal of cigarettes and smokeless tobacco to young people. The proposed rule included a range of restrictions that attempted to preserve the components of advertising and labeling which can provide product information for adult smokers, while eliminating the imagery and color that make advertising appealing to children and adolescents.

Briefly, the final regulation generally limits tobacco advertising in all existing media forms to a black-and-white, text-only format. Outdoor advertising is prohibited within 1,000 feet of public playgrounds, elementary schools or secondary schools. Advertisements in publications read primarily by adults and advertisements placed in adult-only locations are exempt from any advertising restrictions.

Tobacco companies will not be permitted to sell or distribute promotional items such as tee shirts, caps, and sporting goods identified with tobacco products, for example through use of a brand name or logo. Similarly, logos, brand names, and other identifiers of tobacco products cannot be used in sponsorship of musical, cultural, and other events or on teams and entries. However, sponsored events and entries in the

name of a tobacco company may continue

Tobacco products are among the most heavily advertised in this country, accounting for advertising and promotional expenditures of more than $6 billion in 1993.[31] Studies show that tobacco advertising significantly influences children and adolescents in their decision to start smoking or using smokeless tobacco, and it must be considered in any serious effort to reduce tobacco use among youth.

This aspect of FDA's proposal produced substantial comment that either praised the proposed restrictions as critical to reducing the numbers of children and adolescents who begin using tobacco or attacked the advertising provisions as unwise and unconstitutional. Based on its review of the comments, studies, surveys and expert opinion, the agency has refined some of the advertising restrictions to ensure that they are narrowly tailored to achieve FDA's public health objectives.

a. Impact of Advertising

FDA relied heavily on two reports that summarized the evidence concerning the effect of advertising on young people's tobacco use. One came from the Institute of Medicine, and the other was the 1994 Surgeon General's Report. Both reports concluded that advertising was an important factor in young people's tobacco use, and that restrictions on advertising must be part of any meaningful approach to reducing smoking and smokeless tobacco use among young people.

In reviewing the literature, FDA found hundreds of studies examining psychological and social factors affecting tobacco use. These studies were conducted by noted researchers in the fields of medicine, psychology, marketing, public health, and other disciplines, and were published in respected, peer-reviewed scientific journals. Overall, the research provides strong evidence that restrictions on the advertising of cigarettes and smokeless tobacco will serve to protect the health of children and adolescents.

Collectively, the studies show that children and adolescents are widely exposed to, aware of, respond favorably to, and are influenced by cigarette advertising. One study found that 30 percent of 3 year olds and 91 percent of 6 year olds identified Joe Camel as a symbol for smoking.[32] Other studies have shown that young people's exposure to cigarette advertising is positively related to smoking behavior and their intention to smoke. Still others have suggested that cigarette advertising helps young people to decide what is normal or socially acceptable behavior, and that those who overestimate the prevalence of smoking seem to be more likely to begin smoking and progress to regular smoking. Finally, brand advertising appears to be particularly effective with children and adolescents. The three most heavily advertised brands are smoked by 86 percent of young people who smoke; by contrast, adults are far more likely to choose one of the "generic" brands, which are advertised less.[33]

The tobacco and advertising industries were critical of FDA's proposed regulation, focusing their criticism on the failure of the evidence to establish empirically that advertising causes young people to use tobacco, or on whether each proposed restriction would substantially reduce young people's smoking and use of smokeless tobacco. Moreover, they argued that FDA should not eliminate imagery and color since these are essential elements of effective advertising to adults.

In contrast, a comment from the nation's largest psychological association contended imagery and color in advertisements should be eliminated because of their effectiveness in appealing to children. The comment maintained that children generally have less information-processing ability than adults, are less able or less willing to heed the factual information in advertisements, and are less motivated to carefully

consider information such as tar and nicotine content or the Surgeon General's warnings in cigarette and smokeless tobacco advertising.

In the final regulation, FDA narrowed the advertising restrictions as much as possible to retain the informational value that advertising has for adults Information regarding price, tar and nicotine levels, and taste, information typically important to adults who smoke, can be communicated effectively to adults through words alone.

b. The First Amendment

Those opposed to the regulation criticized the proposed rule for violating the First Amendment and understating the protection that commercial speech is afforded. In support of this contention, their comments not only relied on traditional First Amendment jurisprudence, but cited as well to two recent cases, Rubin v. Coors, 115 S. Ct. 1585, and 44 Liquormart, Inc. v. Rhode Island, 116 S. Ct. 1495 (May 13, 1996). FDA in no way underestimates the protection afforded commercial speech, and did weigh its proposal against the Supreme Court's recent rulings in deciding on the provisions of the final rule.

Other comments maintained that tobacco advertising concerns unlawful activity and that therefore it is not protected by the First Amendment. These comments pointed out that it is unlawful in all 50 states to sell tobacco to children under the age of 18. Opponents argued that it is lawful for adults to buy tobacco, and therefore the advertising for those products cannot be considered to be unlawful. Based on its consideration of these arguments, FDA found that a credible basis exists on which to conclude that, at least to the extent that tobacco advertising is related to sale of these products to children under 18, it is not speech protected by the First Amendment.

However, the agency did not rest its regulation solely on this rational, but considered whether the rule meets the standards for regulating commercial speech under the three-prong test established in Central Hudson Gas and Electric Corp. v. Public Service Commission of New York.[34] The agency's analysis under each prong is provided below.

(1) Is the government's interest substantial?
Tobacco use is the leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses.[35] Most people who become addicted to cigarettes begin smoking before they reach the age of 18. [36] Of the one million young people who become regular smokers each year, a third will die prematurely as a result from tobacco use. [37] Even those who opposed the regulation did not seriously contest that the government had a substantial interest in protecting the health of individuals under 18 years of age.

(2) Do the regulations directly advance the government's interest?
Some comments asserted that the agency needs to prove conclusively by empirical evidence that the restrictions that it enacts will completely solve the problem of youth tobacco use. The agency found, based on the available evidence, expert opinion, surveys, and studies, that advertising plays a material role in children's tobacco use, and that the regulation will contribute to a reduction in young people's use of tobacco.

(3) Are the provisions of the regulation are narrowly drawn?
Comments opposing the proposed restrictions asserted that to meet this requirement, the restrictions must be the "least restrictive means" available. In contrast, a number of comments said that to satisfy this requirement, the restrictions must accomplish a "reasonable fit" between the regulation and the

governmental interest to be served. The agency agreed with the latter interpretation, and found that its regulation meets this requirement by restricting only those elements of advertising and promotion that affect young people, while preserving those aspects of advertising that provide information to adults.

c. Major Advertising Provisions

The advertising portion of the final rule contains several major provisions including the following:

1. Billboards Near Schools and Playgrounds

Tobacco advertisements on billboards and other outdoor advertising are prohibited within 1,000 feet of elementary and secondary schools and public playgrounds. These are places where children and adolescents spend a great deal of time, and, thus, where they can be influenced by exposure to advertising.

Some comments asserted that young people do not pay attention to billboards. Other comments said that billboards are unavoidable and should be banned everywhere, not just within 1,000 feet of schools and playgrounds. Evidence of the unavoidability of billboards was found in the outdoor industry's own marketing materials on outdoor advertising, which stated: "Outdoor is right up there. Day and night. Lurking. Waiting for another ambush." [38] However, because of the agency's determination to ensure that its regulations are narrowly tailored, it did not accept these comments.

Moreover, evidence provided in part by the tobacco industry supports the importance of billboards as advertising vehicles for young people. One survey conducted by BKG Youth for Advertising Age showed that 46 percent of children eight to 13 years old said they most often saw cigarette advertising on billboards, out pacing magazines. [39] A study conducted by the R.J. Reynolds Tobacco Company reported that 51 percent of 10-17 year olds surveyed said that they had seen or heard of Joe Camel from a billboard advertisement. [40]

2. Text-only Format

The final rule limits cigarette and smokeless tobacco advertising to black text on a white background, eliminating the imagery and color young people find so appealing. There are, however, two exceptions in which color and imagery in tobacco advertisements are permitted: publications with a primarily adult readership, and adult-only facilities. Adult publications are defined as those: (1) whose readers age 18 or older constitute 85 percent or more of the publication's total readership, or (2) that are read by two million or fewer people under age 18. Based on current readership figures, publications such as Rolling Stone and Sports Illustrated would be limited to text-only advertisements, while Time and Newsweek would be free from restrictions. [41]

Those objecting to this provision said that the text-only restriction was a pretext to banning cigarette advertising generally, and that cigarette advertising does not cause children to start smoking. In contrast, nearly three-quarters of those supporting the text-only provision primarily argued that such action was needed to eliminate the appeal of tobacco products, and that the advertising makes tobacco use more appealing to children and adolescents. The text-only provisions apply to traditional media such as magazines, newspapers and billboards, as well as to direct mail.

3. Sale and Distribution of Non-tobacco Items and Services

The final rule prohibits the tobacco industry from disseminating any non-tobacco item or service that identifies it with tobacco products. This requirement is intended to include such items as tee shirts, caps, sporting goods, and other items that display cigarette brand names or use other ways to connect them with tobacco products. Promotional items are advertisements for these products and very often end up in the hands of young people. A 1992 Gallup survey found that about half of adolescents who smoke and one quarter of adolescents who do not smoke owned at least one of these items. [42]

The agency concluded that a ban of these items was necessary in order to eliminate the appeal that these objects have for young people and to prevent wearers or users of these items from becoming walking advertisements. In addition, the rule prevents a company from offering any gift or item (whether identified with a tobacco brand or not) to any customer. This is essential to prevent the something-for-nothing appeal that such "free" products have for young people.

FDA originally proposed to prohibit the tobacco industry from running contests, lotteries, or games of chance. Because contests, lotteries, and games of chance are already limited to those over 18, and cannot be based on the purchase of a product, the agency has made a change and is not prohibiting them in the final regulation. However, they must follow the rules for advertising and appear in black text on a white background.

4. Sponsorship of Events

The final rule permits tobacco companies to sponsor events, entries, and teams in the corporate name. However, it prohibits tobacco companies from sponsoring any sporting, cultural, or other event in the brand name, logo, colors or anything else that would associate it with particular cigarettes or smokeless tobacco products. In addition, the final rule has been modified to also prohibit tobacco brand name sponsorship of race cars as well as other teams or entries.

Studies show that tobacco-brand sponsorship associates tobacco use with exciting, glamorous, or fun events, such as car racing and rodeos. It also provides an opportunity for "embedded advertising" that actively creates a "friendly familiarity" between tobacco and sports enthusiasts, many of whom are children and adolescents.

The leading source for television viewership estimates that auto racing is watched 64 million times a year by those younger than 18.[43] And unlike print advertisements, which are typically seen for a few seconds, sponsored events with the brand name are viewed for hours at a time.

Further, auto racing, a primary type of tobacco-sponsored event, is becoming increasingly popular with young people, as other corporate sponsors have discovered. According to the president of Hanna-Barbera Cartoons, Inc., the creator of The Flintstones and other cartoons, who recently began sponsoring the "Wacky Racing Team" in the NASCAR Winston Cup Series, "In NASCAR we found a great kids business." [44] Finally, race car drivers are extremely popular with young people and often are looked up to as heroes.[45]

3. Educating Young People About Health Risks

FDA proposed to require tobacco manufacturers to establish and fund a national public education program to counter the effects of the pervasive advertising that for decades has influenced young people to begin and continue using tobacco products.

This approach was based, in part, on historical experience. From July 1, 1967 to December 31, 1970, the Federal Communications Commission, as part of the "Fairness Doctrine," required broadcasters to provide a significant amount of time for anti-smoking messages on television and radio. One anti-smoking message appeared for every three or four industry-sponsored, cigarette advertisements until a ban on all cigarette advertisements on television and radio became effective on January 1, 1971.

For several years, the American public was exposed to both pro- and anti-smoking messages. During this time, per capita cigarette consumption declined 7 percent, from 4,280 in 1967 to 3,985 in 1970. [46] Most of the 7 percent decline (4.5 percent) was attributable to the anti-smoking messages. This was the first time since the early 1930's that per capita consumption declined consecutively for 3 years, and was one of the largest declines ever recorded. Additionally, a study of nearly 7,000 adolescents found that adolescent smoking rates declined during this period. [47] When the anti-smoking messages ended on television and radio, per capita cigarette consumption began to rise.

FDA received many comments on the proposed educational campaign, with the majority favoring the provision. They raised many issues concerning the administration of the program as proposed, including, for example, whether the proposed funding would be equitable or sufficient, and whether industry's level of involvement would jeopardize its effectiveness.

After considering the comments, FDA determined that educating children and adolescents about the unreasonable risks these products pose is analogous to the notification it has required for other devices under section 518(a) of the federal Food, Drug, and Cosmetic Act. In section 518(a) of the act, Congress provided FDA with the authority to require device manufacturers to notify device users about unreasonable risks of substantial harm posed by a device in order to eliminate those risks.

The agency intends to initiate the section 518(a) notification process by sending letters to the six tobacco companies that sell a significant number of tobacco products to young people. These letters will explain why the agency believes that a national, multi-media campaign under section 518(a) to educate young people is necessary to reduce the risks tobacco products pose. The letters will also offer the companies the opportunity to consult with FDA about the necessity, and the scope, of a notification campaign.

4. Additional Requirements

The agency proposed to take additional regulatory action if significant reductions in use of cigarettes and smokeless tobacco among young people were not met within seven years. Based on the comments, the agency has decided to delete this provision. The agency will monitor the effectiveness of the regulations and the extent to which the individual provisions are followed.

5. Relationship Between Regulation And State Laws

Under section 521(a) of the act, state and local requirements pertaining to the sale and distribution of cigarettes and smokeless tobacco that are different from, or in addition to, the federal requirements, are preempted. Most of the state and local laws that would be affected are weaker, for example, state vending machine restrictions. State and local laws unrelated to the rule, such as restrictions on smoking in restaurants, will not be affected. Under section 521(b), state and local governments can submit applications for exemptions from preemption, and FDA is prepared to consider any such applications it receives in an expeditious manner.

6. Analysis of Economic Impact

In financial terms, the rule is expected to produce significant health-related benefits, ranging between $28 billion to $43 billion each year. FDA estimates that the rule will impose one-time costs of between $174 and $187 million, and recurring annual operating costs of between $149 and $185 million. The agency calculated the economic benefits by estimating how many adolescents would not start smoking because of this rule, and then, using existing risk data, predicted how much sickness and death from tobacco products would be prevented. The calculations estimating the cost of implementing the rule were based on comments and several extensive economic reports from the affected industries predicting the rule's impact.

7. Implementation

Most of the provisions of this rule go into effect one year after publication in the *Federal Register.* There are two major exceptions: (1) Six months after publication, retailers must begin enforcing the 18-year-old minimum age of purchase provision by checking purchasers' identification; (2) because most sponsorship contracts are long term, companies will have two years to meet the sponsorship requirements which prohibit sponsorship of events in the name of a tobacco product.

Footnotes

1 Lynch, Barbara S., and Bonnie, Richard J., eds., Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths, Institute of Medicine, National Academy Press, Washington, D.C., 1994. , p.3. (Hereafter referred to as IOM.)

2 "Cigarette Smoking -- Attributable Mortality and Years of Potential Life Lost -- United States, 1990," in MMWR, CDC, DHHS, 42(33):645-649.

3 IOM, op. cit., p. 3.

4 Centers for Disease Control and Prevention, Preventing Tobacco Use Among Young People: A Report of the Surgeon General, U.S. Government Printing Office, Washington, D.C., 1994. p. 5. (Hereafter referred to as SGR 1994.)

5 IOM Report, op. cit., p. 8.

6 Memorandum from Michael P. Ericksen (CDC) to Catherine Lorraine (FDA) August 7, 1995, and CDC Fact Sheet; citing Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, Trends in Cigarette Smoking in the United States: Projections to the Year 2000, JAMA, 261:61-65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Health, "Mortality from Smoking in Developed Countries, 1950-2000: Indirect Estimates from national Vita Statistics," Oxford University Press, Oxford, 1994.

71994 SGR, op. cit., p. 65.

8 The George H. Gallup International Institute, "Teenage Attitudes and Behavior Concerning Tobacco," September 1992. p. 54.

9 Cigarette Smoking Among Adults--United States, 1991, MMWR, DHHS, CDC, vol. 42, No. 12, pp.

230-233, 1993; Johnston, L. D., P. M. O'Malley, and J. G. Bachman, National Survey Results on Drug Use from the Monitoring the Future Study 1975-1993, vol. I: Secondary School Students, Rockville, MD, DHHS, PHS, National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), NIH Pub. No. 94-3809, pp. 9 and 19, 79, 80, 101, 1994, Smoking Rates Climb Among American Teen-agers, Who Find Smoking Increasingly Acceptable and Seriously Underestimate the Risks, The University of Michigan News and Information Service, Table 1., July 17, 1995; Results from the 1995 Monitoring the Future Survey, National Institute on Drug Abuse Briefing for Donna E. Shalala, Secretary of Health and Human Services, December 13, 1995.

10 Johnston, O'Malley, and Bachman, ibid.; Monitoring the Future Survey, 1995, ibid.

11 Kann, L. Et al., Results from the National School-Based 1991 Youth Risk Behavior Survey and Progress Toward Achieving Related Youth Objectives for the Nation, Public Health Reports, vol. 108, (Supp.1), 1993. p. 47-54.

12 National Household Survey on Drug Abuse: Population Estimate 1993, Department of Health and Human Services (DHHS), Public Health Service (PHS), Substance and Mental Health Services Administration (SAMHSA), Office of Applied Studies, Rockville, MD, Pub. No. (SMA) 94-3017, pp. 89 and 95, 1994.

13 Hughes JR, Gust SW, Pechacek TF. Prevalence of tobacco dependence and withdrawal. American Journal of Psychiatry, 1987; 144(2):205-8. ; Woody GE, Cottler LB, Cacciola J. Severity of dependence: data from the DSM-IV field trials. Addiction, 1993; 881573-9.; Cottler L. Comparing DSM-III-R and ICD-10 substance use disorders. Addiction, 1993; 88:689-96.

14 21 U.S.C. 201 et seq.

15 Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination (the 1996 Jurisdictional Determination).

16 DiFranza, J. R., and J. B. Tye, Who Profits from Tobacco Sales to Children? JAMA, 263(20): 2784-2787, 1990.

17 1994 SGR, op. cit. p. 249.

18 U.S. Department of Health and Human Services. Youth Use of Smokeless Tobacco: More Than A Pinch of Trouble. USDHHS, Office of Inspector General. Control No. P-06-86-0058, 1986.

19 Jason, L.A., et al., Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors, JAMA, 266(22):3159-3161, 1991.

20 Erickson, A.D., et. al., A Baseline Assessment of Cigarette Sales To Minors In San Diego, California, Journal of Community Health, 18(4):213-224, 1993.

21 This final rule provides a narrow exception to the minimum package size in response to comments about vending machines that sell packaged single cigarettes.

22 Wilson, D.H., et al., 15s: They Fit in Everywhere-Especially the School Bag: A Survey of Purchases of Packets of 15 Cigarettes by 14 and 15 Year Olds in South Australia, Supplement to Community Health

Studies, vol. XI, No. 1, pp. 16S-20S, 1987

23 1994 SGR, op. cit., p. 249.

24 Response Research, Inc., Study of Teenage Cigarette Smoking and Purchase Behavior, for the National Automatic Merchandising Association, Chicago, p. 23, June/July 1989.

25As with vending machines, FDA will allow the use of self-service displays (merchandisers) in facilities in which retailers ensure that persons under the age of 18 are not present at any time.

26 IOM, op. cit., p. 215, citing Roswell Park Cancer Institute. Survey of Alcohol, Tobacco and Drug Use: Ninth Grade Students in Erie County, 1992. Buffalo, N.Y.: Roswell Park Cancer Institute, Department of Cancer Control and Epidemiology, 1993.

27 Kropp, R., A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vender-Assisted Tobacco Sales, North Bay Health Resources Center, Petaluma, California, November 3, 1994.

28 IOM Report, op. cit., p. 214-215.

29Harshbarger, Scott, Attorney General, Commonwealth of Massachusetts, comment submitted to Proposed Regulations Restriction the Sale and Distribution of Cigarettes and Smokeless Tobacco Products, Docket 95N-0253, number C29885. p. 1.

30 Reducing Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General, DHHS, PHS, CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), OSH, DHHS Pub. No. 89-8411, p. 597, 1989.

31 Report to Congress for 1993, Pursuant to the Federal Cigarette Labeling and Advertising Act, Federal Trade Commission Table 3 and 3D, 1995; Federal Trade Commission Report to Congress: Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986," p. 25-35, 1995.

32 Fischer, P.M., et al., Brand Logo Recognition by Children Aged 3 to 6 Years, JAMA, 266(22):3145-3148, 1991.

33 Changes in the Cigarette Brand Preferences of Adolescent Smokers-United States, 1989-1993, MMWR, CDC, DHHS, 43(32):577-581, 1994.

34 Central Hudson Gas and Electric Corp., v. Public Service Commission of N.Y, 447 U.S. 557 (1980)

35 Cigarette Smoking -- Attributable Mortality and Years of Potential Life Lost -- United States, 1990, MMWR, CDC, DHHS, vol. 42, no. 33. Pp. 645-649.

36 SGR 1994, op. cit., p. 65.

37 op. cit. footnote 6.

38 Outdoor: It's Not a Medium, It's a Large, marketing material produced by the Outdoor Advertising Association of America, Washington, D.C.

39 BKG Youth survey, cited in Advertising Age, April 27, 1992.

40 Roper Starch Worldwide, New York, N.Y., "Advertising Character and Slogan Survey," November, 1993, conduced for the R.J. Reynolds Tobacco Company, Study #343-189. p. 7.

41 Barents Group, LLC, citing Publishers Information Bureau and Mediamark Research, Inc., pp. 53-54.

42 "Teen-Age Attitudes and Behavior Concerning Tobacco-Report of the Findings," The George H. Gallup International Institute, Princeton, N.J., pp 17, 59, September 1992.

43 Slade, John. "Tobacco Product Advertising During Motor Sports Broadcasts: The Quantative Assessment. 9th World Conference on Tobacco and Health, Paris, Oct. 10-14, 1994.

44 "Diamond Ridge Motorosports and Hanna-Barbera, Inc., to form Wacky Racing Team Changing Face of NASCAR; Deal Launches Cartoon Network Consumer Branding Initiative," Business Wire, November 10, 1995.

45 Charlie Cooper, NASCAR properties, quoted in Children's Business, July 1994.

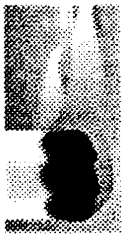
46 Simonich, W. L., Government Antismoking Policies, Peter Lang Publishing, Inc., 1991.

47 Lewit, E.M., D. Coate, and M. Grossman, "The Effects of Government Regulation on Teenage Smoking," Journal of Law and Economics, XXIV(3):545-573. 1981.

FDA HOME PAGE TOBACCO HOME PAGE

Last revised August 1996.

Richmond Times-Dispatch
News Index
Feedback
Gateway Virginia



Tuesday, August 12, 1997

Tobacco regulation clash continues

FDA control is key in appeals court hearing

BY TOM CAMPBELL
Times-Dispatch Staff Writer

WARM SPRINGS -- The cigarette industry and the U.S. government continued their clash over tobacco regulation yesterday before a federal appeals panel sitting in Bath County's smokefree courthouse.

Whether restrictions on the tobacco industry sought by the U.S. Food and Drug Administration will lead to a complete ban of cigarettes and chewing tobacco was key for both sides.

"That's certainly within the agency's authority," acting U.S. Solicitor General Walter C. Dellinger told a three-judge panel of the 4th U.S. Circuit Court of Appeals. But "it would have some bad side effects."

The FDA recognizes the social and economic "dysfunction" a ban would cause and has no such intention, Dellinger argued. The agency wants only to impose its 1996 restrictions aimed at reducing smoking by minors, he said.

Richard Cooper, lawyer for the tobacco makers that sued the FDA, argued that validation of those restrictions by the court would leave nothing to stop the FDA from an outright ban on tobacco. In fact, Cooper argued at one point, a ban is the only action the FDA can properly take, assuming -- as the tobacco industry does not -- that nicotine is a dangerous drug that the FDA can regulate.

Such a sweeping decision must be left to Congress, the tobacco industry lawyer argued.

Both sides are appealing the April ruling by U.S. District Judge William L. Osteen of North Carolina that the FDA can regulate tobacco products. Osteen said "no" only to the FDA restrictions on advertising and marketing methods.

Tobacco companies say Osteen was wrong in saying that the Food, Drug and Cosmetic Act of 1938 authorizes the FDA to regulate nicotine as a drug and cigarettes as "nicotine delivery devices."

The FDA says Osteen was wrong in striking down FDA rules

limiting advertising, sales promotions and sponsorship of sports and entertainment events by tobacco companies.

Yesterday Dellinger argued that the FDA imposed the 1996 regulations because "an extraordinary scientific consensus about these products has emerged" in recent years, proving the strong physiological effects of nicotine.

That, plus evidence that most smokers get hooked before they turn 19, made FDA officials decide to impose restrictions now.

This three-judge panel of the 4th Circuit is hearing cases in Bath County through Thursday. The court, which covers Virginia, West Virginia, Maryland, North Carolina and South Carolina, meets in Richmond and Baltimore most of the year. During the summer, it often schedules hearings in outlying parts of the circuit.

The panel consists of appellate Judges Kenneth K. Hall and Donald S. Russell of the 4th Circuit, and Judge James H. Michael of the Western District of Virginia. Michael was assigned to fill in when the original 4th Circuit judge fell ill.

Frequent questions from the judges suggested they wanted to know why the FDA claims authority now to regulate tobacco when it never has before, despite repeated findings about tobacco's effects.

"What worries us is that from 1938 until a couple of years ago your agency went the other way," Russell said to Dellinger. In fact, the FDA has repeatedly stated tobacco "isn't under our jurisdiction," Russell said.

That's because officials didn't have sufficient information to make the statutory determination that they had jurisdiction over tobacco, Dellinger replied, "but the door was never closed to that."

"We're not claiming that no one knew (smoking) was harmful," Dellinger said. But knowing that was insufficient to invoke the FDA's jurisdiction over nicotine. Now, enough is known about nicotine's powerful physiological effects.

The FDA is supposed to continually look at new findings and decide what should come under its mandate to regulate drugs and devices that affect the function or structure of the human body, Dellinger said.

"But we haven't got any new facts," Russell said. "We've just got the same old nicotine."

Cooper acknowledged that the tobacco company plaintiffs have agreed, as part of this lawsuit, that nicotine has "a variety of effects

on the body," but those effects are not enough to make it a drug as defined in the 1938 law, he said

What is needed is that those effects are intended and claimed by the manufacturer.

Cooper said his tobacco company clients are fighting "an unprecedented . . . and unauthorized assertion of power by a federal agency."

John Fithian, lawyer for a coalition of advertiser groups that have joined this lawsuit, said the FDA advertising restrictions make it an important First Amendment case as well.

He said the FDA is attempting -- "without instructions from Congress" -- to impose "the broadest form of advertising restraint in the history of this country."

Tobacco: Up in smoke? | Metro and Virginia Stories Index

Richmond Times-Dispatch	Feedback	News Index	Gateway Virginia

Appendix 4
Frequently Asked Questions Pertaining to FDA Tobacco Enforcement

U.S. Food and Drug Administration

Children & Tobacco

Frequently Asked Questions

About the New FDA Tobacco Regulations

Draft Guidance

Starting February 28, 1997, new FDA rules prohibit retailers from selling cigarettes,loose cigarette tobacco, and smokeless tobacco to anyone under age 18, and require retailers to verify by means of photo identification the age of anyone under age 27 who wishes to purchase these products. This document answers the questions most frequently asked by retailers, consumers and others about the age and ID restrictions. (The tobacco regulations impose the same restrictions and requirements on loose cigarette tobacco as on cigarettes and smokeless tobacco.)

Litigation

Cigarette and smokeless tobacco manufacturers, trade associations representing advertising agencies and convenience stores, and others sued FDA in Federal District Court arguing that FDA lacked the authority to regulate cigarettes and smokeless tobacco.

Q: What was the recent court ruling in the suit against FDA?

A: On April 25, 1997, Judge William Osteen of the Federal District Court in Greensboro, North Carolina, ruled that FDA has jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act) to regulate nicotine-containing cigarettes and smokeless tobacco. The Court held that tobacco products fit within the the Act's definitions of 'drug' and 'device,' and that FDA can regulate cigarettes and smokeless tobacco products as drug delivery devices under the combination product and restricted device provisions of the Act.

With respect to the tobacco rule, the Court upheld all restrictions involving youth access and labeling, including the two access provisions that went into effect Feb. 28. The Court also upheld access and labeling restrictions originally scheduled to go into effect Aug. 28, 1997, including the prohibition on self-service displays and the placement of vending machines where children have access to them. The Court also upheld the ban on distribution of free samples, the sale of so-called kiddie packs of less than 20 cigarettes, and the sale of individual cigarettes. However, the Court delayed implementation of the provisions that have not yet gone into effect pending further action by the Court.

The Court invalidated on statutory grounds FDA's restrictions on the advertising and promotion of cigarettes and smokeless tobacco. Judge Osteen found that the statutory provision relied upon by FDA, section 520(e) of the Act, does not provide FDA with authority to regulate the advertising and promotion of tobacco products. Specifically, the Court found that the authority in that section to set "such other conditions" on the sale, distribution, or use of a restricted device does not encompass advertising restrictions. Because Judge Osteen based his ruling on the advertising provisions on purely statutory grounds, he declined to consider the First Amendment challenge to those parts of the rule.

The government is appealing the advertising portion of the ruling.

Products Covered

The new regulations apply to cigarettes, loose cigarette tobacco and smokeless tobacco.

Q: Why don't the regulations apply to cigars and pipe tobacco? Given the recent cigar-smoking fad, isn't this an oversight?

A: Unlike the evidence relating to cigarettes and smokeless tobacco, FDA had insufficient evidence at the time the agency proposed these rules that cigars and pipe tobacco are drug delivery devices under the act. Therefore, the agency did not include cigars or pipe tobacco.

Q Are retailers required to card customers under the age of 27 who want to buy rolling papers?

A: No. At this time, retailers are required to card customers under the age of 27 who wish to buy cigarettes, loose cigarette tobacco, or smokeless tobacco, not rolling papers.

Age & ID

Starting February 28, 1997, FDA rules prohibit retailers from selling cigarettes, loose cigarette tobacco, or smokeless tobacco to anyone under the age of 18, and require retailers to check the photo ID of customers under the age of 27.

Q: Who is responsible under the new regulations, the employer or the salesclerk?

A: Under the Federal Food, Drug, and Cosmetic Act, the employer is held responsible for violations of regulations. This result is similar to an employer's responsibilities in other situations involving health and safety requirements. For example, the retailer generally is responsible when an employee's failure to follow health or sanitary codes results in a citation. Similarly, some states and localities revoke a retailer's license to sell tobacco products when a store has a certain number of violations. The penalty against the retailer results from illegal sales made by the store clerks.

Q: Why not penalize the kids who try to buy these products?

A: Some states and localities impose penalties on children under the age of 18 for purchasing, possessing or using tobacco products. FDA's regulations address those responsible for the sale and distribution of these products. FDA believes that it has chosen the most appropriate focus for these regulations.

Q What is the legal age for purchasing cigarettes or smokeless tobacco?

A: Under FDA regulations, a retailer must not sell cigarettes or smokeless tobacco to anyone under 18. Therefore, purchasers must be 18 or older. However, state laws may differ. It is possible that as a result of a companion rulemaking, FDA may permit states to enforce a higher age requirement for the purchase of these products.

Q: Why did FDA decide that retailers must require customers under the age of 27 to present a photo ID?

A: It is very difficult to judge the age of many teenagers and young adults simply from their appearance, partly because young people mature at different rates To ensure that older-looking teenagers are asked for ID, it makes common sense to set the requirement to check identification somewhere above 18. This reasoning is reflected in a report prepared by twenty-six State Attorneys General recommending that the age for photo ID should be significantly higher than the minimum age of sale. In addition, materials developed and distributed to retailers by the tobacco industry and leading retailer organizations specifically recommended that retailers card anyone who appears to be under 26.

Q: Does a retailer have to check the ID of regular customers who are known to be at least 18 years old every time they buy one of these products?

A: No. Retailers must check a customer's photo ID at least once to ensure that the customer is at least 18 years old.

Q: Some states do not require photographs on their driver's licenses. What type of ID should purchasers present in such states?

A: The rule does not require that customers present a driver's license. While any form of ID which contains a photograph and the birth date of the bearer is acceptable, the agency suggests that retailers request a government-issued photo ID, such as a driver's license, passport, or military ID, because they are more reliable and more difficult to alter.

Q: What should a salesclerk do when the clerk suspects that a customer's ID is fake or has been altered?

A: If a retailer suspects that an ID is unreliable, the retailer should refuse the sale. Selling to an underage customer violates the rule. However, if an underage customer presents a fake or altered ID, and the retailer reasonably relies in good faith on the ID, FDA will not bring a compliance action. Fake ID cards may be difficult to detect, but many fake cards are obvious due to their poor quality. There are also some companies that sell manuals showing pictures of current, valid driver's licenses for each state. These manuals may help the retailer to determine whether or not an ID card is valid.

Q: Can a retailer accept an out-of-state driver's license if it has the customer's picture and date of birth?

A: Yes. The rule states that any photo ID with a birth date is acceptable.

Q: Can a retailer sell to a child whose parent sends the child into a store to buy these products for the parent?

A: No. FDA's rule prohibits retailers from selling to anyone under 18, and requires retailers to demand proof-of-age. So parents need to purchase tobacco products for themselves.

Q: Is a retailer responsible for preventing parents or other adults from purchasing tobacco products for minors?

A: No. While the retailer is free to refuse the sale, the rule only requires that the retailer verify the age of the purchaser.

Q: Does a salesclerk have to be at least 18 years old to sell cigarettes?

A: No. FDA's regulations do not address the age of the salesclerk, although some state laws may require a minimum age for salesclerks.

Tobacco Shops, Wholesalers & Indian Reservations

The age and ID requirements apply to retailers who sell cigarettes or smokeless tobacco to consumers for their personal use.

Q: How do the regulations affect those retailers who sell only tobacco products?

A: Retailers that sell only tobacco products are subject to the same age and photo identification requirements as other retailers.

Q: If a wholesale operation delivers to a store or gas station, and the only employee present at the time of delivery is someone under 18, can the delivery be made?

A: Yes. The wholesaler is selling to a retailer, not to a consumer. Therefore, under FDA's rule, a person of any age can sign or pay for the delivery on behalf of the retailer, and that would not constitute a violation. However, state or local laws may prohibit the delivery of tobacco products to persons younger than a certain age.

Q: Do FDA's tobacco regulations apply to sales of cigarettes and smokeless tobacco on Indian reservations?

A: As a general rule, statutes that by their terms apply to everyone generally are presumed to apply to Indian reservations. This general rule can be altered by specific treaties with individual tribes. FDA's Compliance Policy Guide provides that "FDA considers Indian Reservations to be possessions of the United States within the meaning of [the act]." Therefore, FDA presumes that the tobacco regulations apply to sales of cigarettes and smokeless tobacco on Indian reservations unless a specific treaty with an individual tribe alters FDA's jurisdiction over such sales.

Enforcement

To ensure that the federal rule is followed, FDA will contract with the states to carry out compliance checks during which adolescents, accompanied by state or local officials commissioned by FDA, will attempt to purchase cigarettes and smokeless tobacco from retailers.

Q: How does a compliance check work?

A: FDA will train state officials and provide them with a manual that defines how compliance checks are

to be conducted. Generally, a minor accompanied by a commissioned state or local official will enter a retail establishment and attempt to purchase cigarettes or smokeless tobacco. All results will be reported to FDA.

Q: What happens to retailers who do not card someone between 18 and 27 before selling them cigarettes or smokeless tobacco?

A: If FDA receives a complaint that a retailer is not checking IDs for young people under 27, it will not result in a monetary penalty. However, FDA will use these complaints for scheduling retailers for a compliance check, using a minor to ensure that the retailer is not selling to minors.

Q: Why don't you cite a violator on the spot?

A: First, FDA chose not to issue letters on the spot out of concern for the safety of the adolescent and official conducting the compliance check. Second, FDA believes the compliance checks will be more effective if they are unannounced. If letters were given on the spot, retailers in the community would get word that compliance checks were underway in their area.

Q: How many times will FDA visit a retailer to conduct a compliance check?

A: Once we have determined that a retailer has violated the regulations, we'll keep going back until the retailer demonstrates compliance with the regulations. Therefore, retailers that have a record of noncompliance with FDA's requirements should expect to be investigated more frequently than those who have a history of complying with the regulations.

Q: Will FDA notify retailers who are found to be in compliance?

A: Yes. We intend to recognize retailers who refuse to sell tobacco products to the minors that participate in our compliance checks. We plan to send a letter stating that the retailer was found to be in compliance with the final rule. Those letters will be publicly available and communities will be able to recognize retailers that refuse to sell to minors.

Q: When will the enforcement operation begin?

A: We expect that the first compliance checks will be conducted in Summer 1997.

Q: Can any non-government group conduct compliance checks for FDA?

A: No. Only those state or local officials authorized by FDA will be able to conduct compliance checks for FDA.

Q: What can a state or local law enforcement officer do if the officer witnesses an illegal sale?

A: State or local officers can enforce their state or local law, depending on the officer's jurisdiction, and can report to FDA any violation of FDA's rules. However, an officer can only conduct compliance checks for FDA if the officer has been commissioned by FDA.

Q: How much time will there be between the first letter notifying a retailer that a violation has occurred, and the second or follow-up compliance check?

A: FDA will give retailers a reasonable amount of time to come into compliance before scheduling a follow-up visit, but the exact amount of time is likely to depend on a number of variables and will vary from state to state.

Q: Will letters to merchants and penalties sought come from FDA?

A: Yes. For compliance checks conducted by FDA commissioned officials, FDA will send a letter either acknowledging a retailer's refusal to sell to a minor notifying the retailer of a first violation, or seeking penalties for a second or subsequent violation. FDA will seek penalties only for violations observed and documented during compliance checks conducted by or for FDA. FDA intends to mail letters as soon after receiving reports from commissioned officials as is practicable. Retailers also may receive correspondence from state or local officials for violations of state or local law.

Q: Will the employee making the sale be identified in the FDA letter?

A: No. However, FDA will mail to retailers a copy of the form that will contain the date and time of the violation and the gender of the salesclerk who sold to the adolescent.

Q: What can a customer do if the customer continues to see repeated offenses?

A: First, a customer could complain directly to the retailer, reminding the retailer of the new federal rule. Second, the customer could report the retailer to FDA's hotline and to state and local authorities.

Q: How will FDA guard against false complaints?

A: As with any hotline, it will not be possible for FDA to determine whether a false complaint was filed. However, the complaint itself is not sufficient to trigger a letter notifying a retailer of a violation or a penalty proceeding. A complaint prompts FDA to schedule a compliance check as soon as practicable and, if the store is not selling to minors, it will not be subject to any sanctions.

Q: If FDA conducts a compliance check based on a report of an alleged violation and finds that the retailer is in compliance, how many times will FDA continue to investigate the retailer?

A: If FDA finds a retailer in compliance, the retailer would be randomly selected for its next investigation, unless FDA received another complaint.

Q: What is the penalty for a first violation?

A: The first time FDA finds a retailer to be in violation, FDA will send a letter explaining the new rules, describing the violation, and informing the retailer that another compliance check will be scheduled. The second time a retailer is in violation, FDA will seek civil money penalties in the amount of $250.00. For subsequent violations, FDA will seek higher penalties.

Q: Why doesn't FDA suspend or revoke retailers' right to sell tobacco products for repeated violations?

A: Some states and localities have issued licenses to sell tobacco products and revoke licenses for repeated violations. This has been shown to be an effective means of enforcing tobacco control laws. However, historically, this has been a matter that falls under state or local jurisdiction.

Q: Will the agency seek penalties against chain stores with a particularly poor compliance record?

A: FDA believes that corporations and franchises have an important role in ensuring that their stores understand and comply with the new rules. Therefore, FDA currently is considering an enforcement strategy for these organizations that will both recognize a high rate of compliance among the stores in an organization and seek penalties against the corporation or franchisor for a low rate of compliance among their stores.

Q: If FDA contracts with state or local agencies to conduct compliance checks, can the state or local authority use that information to take action under their own laws?

A: Yes. As is sometimes the case, a single act may violate local, state and federal law. Therefore, even though FDA will mail a letter for a first violation, the state or local authority may impose state or local sanctions. Similarly, FDA may seek civil money penalties for a violation that also is subject to state or local sanctions.

Q: What are the procedures for contesting and appealing a civil money penalty?

A: The procedures for the civil money penalty actions, including appeals, are explained in 21 Code of Federal Regulations (CFR) Part 17. Many libraries have the CFR, or you can find it on the Internet at http://www.access.gpo.gov.

Q: What happens if a retailer fails to pay the penalty?

A: If, after a civil money penalty assessment becomes final, the retailer refuses to pay, the U.S. Department of Justice may sue the retailer in federal court under the Food, Drug, and Cosmetic Act for the amount of the penalty plus interest.

Q: Does FDA keep the funds collected from penalties?

A: No. All civil money penalties collected by FDA will be deposited as miscellaneous receipts in the Treasury of the United States.

Although this guidance document does not confer any rights for or on any person and does not operate to bind FDA or the public, it does represent the agency's current thinking on the regulations involving the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents at 21 CFR Part 897. Alternative methods that comply with the tobacco regulations are acceptable. If a regulated company or person wishes or chooses to use an approach other than that set forth in this guidance document, FDA will, upon request, discuss with that company or person alternative methods of complying with the regulations.

FDA is accepting public comment on this document. You can submit written comments to: Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr.,Room 1-23, Rockville, MD 20857.

Comments should be identified with docket number 97D-0261 and will be available for viewing at the Dockets Management Branch from 9 a.m. to 4 p.m., Monday through Friday.

Last revised July 1997.

Appendix 5
Full Text for Proposed Tobacco Settlement

(also available as a PDF file which requires (the free) Adobe Acrobat plug-in)

(Table of contents)

PROPOSED RESOLUTION

PREAMBLE

This legislation would mandate a total reformation and restructuring of how tobacco products are manufactured, marketed and distributed in this country. The nation can thereby see real and swift progress in preventing underage use of tobacco, addressing the adverse health effects of tobacco use and changing the corporate culture of the tobacco industry.

The Food and Drug Administration ("FDA") and other public health authorities view the use of tobacco products by our nation's children as a "pediatric disease" of epic and worsening proportions that results in new generations of tobacco dependent children and adults. There is also a consensus within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease and other serious adverse health effects.

The FDA and other health authorities have concluded that virtually all new users of tobacco products are under legal age. President Clinton, the FDA, the Federal Trade Commission ("FTC"), state Attorneys General and public health authorities all believe that tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents. These officials have concluded that because past efforts to restrict advertising and marketing have failed to curb adolescent tobacco use, sweeping new restrictions on the sale, promotion and distribution of such products are needed.

Until now, federal and state governments have lacked many of the legal means and resources they need to address the societal problems caused by the use of tobacco products. These officials have been armed only with crude regulatory tools which they view as inadequate to achieve the public health objectives with which they are charged.

This legislation greatly strengthens both the federal and state governments' regulatory arsenal and furnishes them with additional resources needed to address a public health problem that affects millions of Americans, including most importantly underage tobacco use. Further, it is contemplated that certain

of the obligations of the tobacco companies will be implemented by a binding, enforceable contractual protocol.

The legislation reaffirms individuals' right of access to the courts, to civil trial by jury and to full compensatory damages. Resolution through the Act of potential punitive damages liability of the tobacco industry for past conduct is only made in the context of the comprehensive settlement proposed by the legislation. It is not intended to have precedential effect, nor does it express any position adverse to the imposition of punitive damages in general or as applied to any other specific industry, case, controversy or product and does not provide any authority whatsoever regarding the propriety of punitive damages.

Among other things, the new regime would:

-- Confirm FDA's authority to regulate tobacco products under the Food, Drug and Cosmetic Act, making FDA not only the preeminent regulatory agency with respect to the manufacture, marketing and distribution of tobacco products but also requiring the tobacco industry to fund FDA's oversight out of ongoing payments by the manufacturers pursuant to the new regime ("Industry Payments").

-- Go beyond FDA's current regulations to ban all outdoor tobacco advertising and to eliminate cartoon characters and human figures, such as Joe Camel and the Marlboro Man, two tobacco icons which the public health community has long assailed as advertising appealing to our nation's youth.

-- Impose and provide funding out of the Industry Payments for an aggressive federal enforcement program, including a State-administered retail licensing system, to stop minors from obtaining tobacco products, while in no way preventing the States from enacting additional measures.

-- Ensure that the FDA and the States have the regulatory flexibility to address issues of particular concern to public health officials, such as youth tobacco usage and tobacco dependence.

-- Subject the tobacco industry to severe financial surcharges in the event underage tobacco use does not decline radically over the next decade.

-- Empower the federal government to set national standards controlling the manufacturing of tobacco products and the ingredients used in such products.

-- Provide new and flexible regulatory enforcement powèrs to ensure that the

tobacco industry works to develop and introduce less-hazardous tobacco products," including, among other things, vesting FDA with the power to regulate the levels of nicotine in tobacco products.

-- Require the manufacturers of tobacco products to disclose all previously non-public internal laboratory research and all new internal laboratory research generated in the future relating to the health effects or safety of their products.

-- Establish a minimum federal standard with tough restrictions on smoking in public places with enforcement funding from the Industry Payments, while preserving the authority of state and local governments to enact even more severe standards.

Authorize and fund from Industry Payments a $500 million annual, national education-oriented counter-advertising and tobacco control campaign seeking to discourage the initiation of tobacco use by children and adolescents and to encourage current tobacco product users to quit use of the products.

-- Authorize and fund from Industry Payments the annual payment to all States of significant, ongoing financial compensation to fund health benefits program expenditures and to establish and fund a tobacco products liability judgments and settlement fund.

-- Authorize and fund from Industry Payments a nationwide program, administered through State governments and the private sector, of smoking cessation.

The sale of tobacco products to adults would remain legal but subject to restrictive measures to ensure that they are not sold to underage purchasers. These measures respond directly to concerns voiced by federal and state public health officials, the public health community and the public at large that the tobacco industry should be subject to the strictest scrutiny and regulatory oversight. This statute imposes regulatory controls, including civil and criminal penalties, equal to, and in many respects exceeding, those imposed on other regulated industries. Further, it imposes on tobacco manufacturers the obligation to provide funding from Industry Payments for an array of public health initiatives.

The sale, distribution, marketing, advertising and use of tobacco products are activities substantially affecting interstate commerce. Such products are sold, marketed, advertised and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the nation's economy. The sale,

distribution, marketing, advertising and use of such products are also activities substantially affecting interstate commerce by virtue of the health care and other costs that federal and State governmental authorities have attributed to usage of tobacco products.

Various civil actions are pending in state and federal courts arising from the use, marketing or sale of tobacco products. Among these actions are cases brought by some 40 state Attorneys General, cases brought by certain cities and counties, the Commonwealth of Puerto Rico, and other third-party payor cases seeking to recover monies spent treating tobacco-related diseases and for the protection of minors and consumers. Also pending in courts throughout the United States are various private putative class action lawsuits brought on behalf of individuals claiming to be dependent upon and injured by tobacco products. Additionally, a multitude of individual suits have been filed against the tobacco products manufacturers and/or their distributors, trade associations, law firms and consultants.

All of these civil actions are complex, slow-moving, expensive and burdensome, not only for the litigants but also for the nation's state and federal judiciaries. Moreover, none of those litigation's has to date resulted in the collection of any monies to compensate smokers or third-party payors. Only national legislation offers the prospect of a swift, fair, equitable and consistent result that would serve the public interest by (1) ensuring that a portion of the costs of treatment for diseases and adverse health effects linked to the use of tobacco products is borne by the manufacturers of these products, and (2) restricting nationwide the sale, distribution, marketing and advertising of tobacco products to persons of legal age. The unique position occupied by tobacco in the nation's history and economy, the magnitude of actual and potential tobacco-related litigation, the need to avoid the cost, expense, uncertainty and inconsistency associated with such protracted litigation, the need to limit the sale, distribution, marketing and advertising of tobacco products to persons of legal age, and the need to educate the public, especially young people, of the health effects of using tobacco products all dictate that it would be in the public interest to enact this legislation to facilitate a resolution of the matters described.

Public health authorities believe that the societal benefits of this legislation, in human and economic terms, would be vast. In particular, FDA has found that reducing underage tobacco use by 50% "would prevent well over 60,000 early deaths." FDA has estimated that the monetary value of its present regulations will be worth up to $43 billion per year in reduced medical costs, improved productivity and the benefit of avoiding the premature death of loved ones. This statute, which extends far beyond anything FDA has previously proposed or

attempted, can be expected to produce human and economic benefits many times greater than such existing regulations.

As part of this settlement, the tobacco companies recognize the historic changes that will be occurring to their business. They will fully comply with increased federal regulation, focus intense efforts on dramatic reductions in youth access and youth tobacco usage, recognize that the regulatory scheme encourages the development of products with reduced risk and acknowledge the predominant public health positions associated with the use of tobacco products.

[Source/precedent: FDA Rule]

Contents

Title VI: Programs/Funding

A. Up Front Commitment
B. Base Annual Payments
C. Applicability
D. Tax Treatment

Title VII: Public Health Funds From Tobacco Settlement As Recommended by The Attorneys General For Consideration by the President and the Congress

Title VIII: Civil Liability

A. General
B. Provisions as to Civil Liability for Past Conduct
C. Provisions as to Civil Liability for Future Conduct

Title IX: Board Approval

Appendices:

Appendix I: Warnings in Advertisements

Appendix II: Retail Tobacco Product Seller Penalties

Appendix III: Application to Indian Tribes

Appendix IV: Industry Associations

Appendix V: "Look Back"

Appendix VI: State Enforcement Incentives

Appendix VII: Restrictions on Point of Sale Advertising

Appendix VIII: Public Disclosure of Past and Future Tobacco Industry Documents and Health Research

---

TITLE I: Reformation Of The Tobacco Industry

Title I of the legislation would incorporate and expand upon FDA's recent regulation of nicotine-containing tobacco products.

The following rules would apply to all tobacco products sold in the U.S. (including all its territories and possessions, as well as duty-free shops within U.S. borders). The new regime would be allowed to operate as described below for five years. FDA would have authority to make revisions even within this period under extraordinary circumstances. Thereafter, the FDA would be authorized to review and revise the rules under applicable Agency procedures.

A. Restrictions on Marketing and Advertising

The advertising and marketing of tobacco products would be drastically curtailed, including in ways that exceed the FDA rule as originally promulgated and in ways that have previously been challenged on First Amendment grounds. As in the FDA rule the new regime would:

-- Prohibit the use of non-tobacco brand names as brand names of tobacco products except for tobacco products in existence as of January 1,1995 (897.16(a)) (The citations in this and in the next section are to Part 897 of the FDA's tobacco regulations, 61 Fed. Reg. 44396 (August 28, 1996).

-- Restrict tobacco product advertising to FDA specified media (897.30(a)(1)-(2))

-- Restrict permissible tobacco product advertising to black text on a white background except for advertising in adult-only facilities and in adult publications (897.32(a)-(b))

-- Require cigarette and smokeless tobacco product advertisements to carry the FDA-mandated statement of intended use ("Nicotine Delivery Device") (897.32(c))

-- Ban all non-tobacco merchandise, including caps, jackets or bags bearing the name, logo or selling message of a tobacco brand (897.34(a)).

-- Ban offers of non-tobacco items or gifts based on proof of purchase of tobacco products (897.34(b))

-- Ban sponsorships, including concerts and sporting events, in the name, logo or selling message of a tobacco brand (897.34(c))

Further, building on and going beyond the FDA rule, the new regime would:

-- Ban the use of human images and cartoon characters - thereby eliminating Joe

Camel and the Marlboro Man - in all tobacco advertising and on tobacco product packages

-- Ban all outdoor tobacco product advertising, including in enclosed stadia as well as brand advertising directed outside from a retail establishment (modifies 897.30(a)(1) and extends 897.30(b))

-- Prohibit tobacco product advertising on the Internet unless designed to be inaccessible in or from the United States

-- Establish nationwide restrictions in non adult-only facilities on point of sale advertising with a view toward minimizing the impact of such advertising on minors. These provisions, which are detailed in Appendix VII, restrict point of sale advertising that was otherwise permitted in retail establishments by the FDA rule.

-- Ban direct and indirect payments for tobacco product placement in movies, television programs and video games

-- Prohibit direct and indirect payments to "glamorize" tobacco use in media appealing to minors, including recorded and live performances of music -- Without limiting the FDA's normal rulemaking authority in this area, require that the use, in both existing and future brand styles, of words currently employed as product descriptors (e.g., "light" or "low tar") be accompanied by a mandatory disclaimer in advertisements (e.g., "Brand X not shown to be less hazardous than other cigarettes"); exemplars of all new advertising and tobacco products labeling shall be submitted to FDA concurrently with their introduction into the marketplace for FDA's ongoing review.

[Source/precedent: FDA Rule; 21 C.F.R. 101.70]

B. Warnings, Labeling and Packaging

The federally-mandated warning labels on cigarettes were last changed in 1984. Since then a number of countries, including Canada and members of the European Union, have imposed new warning labels. Further, the Federal Trade Commission's methodology to measure the "tar" and nicotine yields of cigarettes has been criticized as producing misleading information.

1. The legislation, through amendments to the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, would mandate new rotating warnings, to be introduced concurrently into

the distribution chain on all tobacco product packages and cartons, and to be rotated quarterly in all advertisements. For cigarettes, the warnings would be:

-- "WARNING: Cigarettes are addictive"

-- "WARNING: Tobacco smoke can harm your children"

-- "WARNING: Cigarettes cause fatal lung disease"

-- "WARNING: Cigarettes cause cancer"

-- "WARNING: Cigarettes cause strokes and heart disease"

-- "WARNING: Smoking during pregnancy can harm your baby"

-- "WARNING: Smoking can kill you"

-- "WARNING: Tobacco smoke causes fatal lung disease in non-smokers"

-- "WARNING: Quitting smoking now greatly reduces serious risks to your health"

For smokeless tobacco products, the warnings would be:

-- "WARNING: This product can cause mouth cancer"

-- "WARNING: This product can cause gum disease and tooth loss"

-- "WARNING: This product is not a safe alternative to cigarettes"

--"WARNING: Smokeless tobacco is addictive"

For cigarettes, the warnings would occupy 25% of the front panel of the package (including packs and cartons) and would appear on the upper portion thereof. The legislation would contain a grandfather provision for existing brands with flip-top boxes comprising less than 25% of the front panel. For smokeless tobacco products, the warnings would appear on the principal display panel (e.g., a band around the can for moist smokeless tobacco products) and would occupy 25% of the display panel. The warnings would be printed in line with current Canadian standards (e.g., 17 point type with appropriate adjustments depending on length of required text) and in an alternating black on white and white on black format. The size and placement of warnings in advertisements would follow the requirements set forth in the existing United

Kingdom standards. As described in Appendix I, the warning text and, where relevant, "tar" and nicotine (or other constituent) yield information would occupy 20% of press advertisements.

Cigarette and smokeless tobacco product packages would also carry the FDA mandated statement of intended use ("Nicotine Delivery Device") on the side of pack.

2. The FDA would be required to promulgate a rule governing the testing, reporting and disclosure of tobacco smoke constituents that the Agency determines the public should be informed of to protect public health, including, but not limited to "tar," nicotine and carbon monoxide. This authority would be transferred from the FTC and would include the authority to require label and advertising disclosures relating to "tar" and nicotine, as well as disclosures by other means relating to other constituents.

[Source/precedent: Canadian warning regulations; FDA Rule; FDCA, 21 U.S.C. Sec. 360h, with conforming amendment in light of FCLAA]

C. Restrictions on Access to Tobacco Products

Preventing youth access to tobacco products is a major objective of this legislation and the FDA Rule. Without preventing state and local governments from imposing stricter measures, the legislation would incorporate every access restriction of the FDA Rule, and more. As in the FDA Rule, the legislation would:

-- Set a minimum age of 18 to purchase tobacco products (897.14(a))

-- Require retailers to check photo identification of anyone under 27 (897.14(b)(1)-(2))

-- Establish the basic requirement of face-to-face transactions for all sales of tobacco products (897.14(c))

-- Ban the sale of tobacco products from opened packages (897.14(d))

-- Establish a minimum package size of 20 cigarettes (897.16(b))

-- Impose retailer compliance obligations to ensure that all self-service displays, advertising, labeling and other items conform with all applicable requirements (897.14(e))

-- Ban the sampling of tobacco products (897.16(d))

-- Ban the distribution of tobacco products through the mail, including redemption of coupons, except for sales subject to proof of age, with a review after 2 years by FDA to determine if minors are obtaining tobacco products through the mail (goes beyond 897.16(c)(2)(i))

Building on and going beyond the FDA Rule, the legislation would:

-- Ban all sales of tobacco products through vending machines (goes beyond 897.16(c)(2)(ii))

-- Ban self-service displays of tobacco products except in adult-only facilities. In all other retail outlets, tobacco products must be placed out of reach of consumers (i.e., behind the counter or under lock-and-key) or, if on the counter, not visible or accessible to consumers (goes beyond (897.1 6(c)(2)(ii))

[Source/precedent: FDA Rule]

D. Licensing of Retail Tobacco Product Sellers

The legislation would mandate minimum federal standards for a retail licensing program that the federal government and state and local authorities would enforce through funding provided by the Industry Payments. Any entity that sells directly to consumers - whether a manufacturer, wholesaler, importer, distributor or retailer -would require a license.

Elements of the licensing program would include:

-- Mandating compliance with the Act as a condition to obtain and hold a license

-- Penalties for violations (See Appendix II)

-- Suspension or revocation of licenses (on a site-by-site basis) for certain violations (see Appendix II)

-- A requirement that distribution of tobacco products for resale to consumers be made only to licensed entities

-- Licensing fees to cover the administrative costs of issuing state licenses (all

other costs covered as noted above)

-- Comparable federal licensing programs (with federal enforcement) for military facilities, U.S. government installations abroad, and other U.S. territories and possessions not otherwise under the jurisdiction of the States (including duty-free shops within U.S. borders)

-- Comparable licensing programs to govern tobacco product sales on Indian lands (see Appendix III)

(Source/precedent: Various state laws governing sales of tobacco products and alcoholic beverages)

E. Regulation of Tobacco Product Development and Manufacturing

This legislation, for the first time, would impose a regulatory regime to govern the development and manufacturing of cigarettes and smokeless tobacco products, including FDA approval of the ingredients used in such products and imposition of standards for reducing the level of certain constituents, including nicotine.

Elements of the regulatory regime would include:

1. Tobacco products shall have the same definition as contained in the FDA Rule. Jurisdiction shall also cover Roll Your Own, Little Cigars, Fine Cut, etc.

2. Tobacco will continue to be categorized as a "drug" and a "device" under the Food, Drug and Cosmetic Act ("FDCA"). The Agency's authority to regulate the products as restricted medical devices" will be explicitly recognized and tobacco products will be classified as a new subcategory of a Class II device pursuant to 21 U.S.C. section 360c. FDCA shall apply to these products as provided by the Act and the amendments to FDCA contained herein.

3. The Class II classification shall permit FDA to require product modification of tobacco products, including the regulation of nicotine content, and shall provide that the sale of tobacco products to adults in the form that conforms to Performance Standards established for tobacco products pursuant to Section 514 ("Section 514") of the FDCA (21 U.S.C. Section 360d) shall be permitted notwithstanding 21 U.S.C. Sections 360f, 352(j) and 360h(e)

4. Reduced Risks Products

Products sold that an objective, reasonable consumer would believe pose less of

a health risk:

-- Tobacco product manufacturers will be barred from making claims that could reasonably be interpreted to state or imply a reduced health risk unless the manufacturer demonstrates to FDA that the product scientifically does in fact "significantly reduce the risk to health" from ordinary tobacco products. Currently employed product descriptors such as "light" and "low tar" will be regulated as described in 1(A) above.

-- FDA would have to approve all health claims (direct or implied), as well as the content and placement of any such claims in advertisements, to prevent the public from being misled and to prevent the advertisement from being used to expand, or prevent the contraction of, the marketplace.

-- For "less hazardous tobacco products," FDA will be authorized to permit scientifically-based specific health claims and to permit exceptions to the advertising restrictions that apply to other products if FDA determines that such advertising would reduce harm and promote the public health. The FDA will promulgate a rule to govern how these determinations will be made.

-- The manufacturers will be required to notify FDA of any technology that they develop or acquire and that reduces the risk from tobacco products and, for a commercially reasonable fee, to cross license all such technology, but only to those companies also covered by the same obligations. Procedural protections will be built in to resolve license fee disputes, if the private parties cannot agree among themselves first. If the technology reported to the FDA is in the early development stages, the manufacturer will be provided confidentiality protection during the development process.

-- The Agency shall also have the authority to mandate the introduction of "less hazardous tobacco products" that are technologically feasible, after a formal rule making subject to the Administrative Procedures Act ("APA"), with the right of judicial review. In doing so, the Agency shall have the authority to mandate that a manufacturer subject to this Act who owns such technology (at such manufacturer's election) either introduce such products, or, at a commercially reasonable market rate, license such technology to a manufacturer who agrees to bring the technology to market in a reasonable time frame. In the event that no manufacturer or licensee introduces such "less hazardous tobacco products," within a reasonable time frame set by FDA, then the U.S. Public Health Service may produce either itself, or through a licensing arrangement, any such product.

-- The goal of any rule mandating the introduction into the marketplace of "less

hazardous tobacco products" for which the technology exists is to guarantee that a mechanism exists to ensure that products which appear to hold out the hope of reducing risk are actually tested and made available in the marketplace and not held back.

5. Performance Standards

To further the public health, to promote the production of "reduced risk" tobacco products, and to minimize the harm to consumers of tobacco products by insuring that the best available, feasible safety technology becomes the industry standard, FDA will have the authority to promulgate Performance Standards pursuant to Section 514 that require the modification of tobacco products to reduce the harm caused by those products (including the components that produce drug dependence), provided that the standard shall not require the prohibition on the sale to adults of traditional tobacco products in the basic form as described in the August 28, 1996 FDA Rule at 61 Fed. Reg. at 44616 (to be codified at 21 C.F.R. Section 897.3).

Specifically:

A. For a period of no fewer than twelve years following the effective date of the Act, the product Performance Standards will be governed by the following: The Agency shall be permitted to adopt performance standards that require the modification of existing tobacco products, including the gradual reduction, but not the elimination, of nicotine yields, and the possible elimination of other constituents or other harmful components of the tobacco product, based upon a finding that the modification: (a) will result in a significant reduction of the health risks associated with such products to consumers thereof, (b) is technologically feasible, and (c) will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard. In determining the risk of the demand for a market in contraband products, the FDA shall take into account the number of dependent tobacco product users and the availability, or lack thereof, of alternative products then on the market and such other factors as the Agency may deem relevant.

The authority to require such product modification can be exercised upon a showing of "substantial evidence," based upon an administrative record developed through a formal rule making subject to the Administrative Procedures Act, with the right of judicial review, and any such modification shall be subject to the current procedures of the Regulatory Reform Act of 1996 to provide time and a process for Congress to intervene should it so choose. In

the event a party subsequently files a petition seeking an administrative review of whether a modification has, in fact, resulted in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard and FDA denies the petition, the petitioner shall have the right to seek judicial review of the denial of the petition.

Additionally:

-- Within one year of the effective date of this Act, the FDA shall establish a Scientific Advisory Committee to examine and determine the effects of the alteration of nicotine yield levels and to examine and determine whether there is a threshold level below which nicotine yields do not produce drug dependence and, if so, to determine that level, and also review any other safety, dependence or health issue so designated by FDA.

-- Separate from and without detracting from the Agency's authority under the requirements of the Section 514 Performance Standard noted above, effective three years from the date of enactment of this Act, no cigarette shall be sold in the United States which exceeds a 12 mg "tar" yield, using the testing methodology now being used by the Federal Trade Commission.

B. After the initial twelve year period, the Agency will be permitted to set product safety standards that go beyond the standards it is authorized to set pursuant to the above noted provisions and, if it does so, any such product Performance Standards shall be governed by the following: The Agency will be permitted to require the alteration of tobacco products then being marketed, including the elimination of nicotine and the elimination of other constituents or other demonstrated harmful components of the tobacco product, (the elimination of nicotine or other harmful constituent shall not be deemed to violate the prohibition on the sale of traditional tobacco products to adults, even if it results in a reduction of the number of the consumers who use the tobacco products then remaining on the market), based upon a finding that: (a) the safety standard will result in a significant overall reduction of the health risks to tobacco consumers as a group, (this includes the reduction in harm which will result from decreased drug dependence from the reduction and/or elimination of nicotine from (a) those who continue to use tobacco products, but less often, and (b) those who stop using tobacco products), (b) the modification is technologically feasible, and (c) the modification will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard. In determining the overall health benefit of a change, the Agency shall consider the number of dependent tobacco users then in existence, the availability and demonstrated market acceptance of alternate products then on the market, and the effectiveness of smoking cessation

techniques and devices then on the market and such other factors as the Agency may deem relevant.

Given the significance of such an action, the Agency will be permitted to require the elimination of nicotine or take such other action that would have an effect comparable to the elimination of nicotine based upon a "preponderance of the evidence" pursuant to, at a manufacturer's election, a Part 12 hearing, or notice and comment rule making, with a right of judicial review. Any such action shall be phased in, and no such phase-in shall begin in less than two years, to permit time for a meaningful Congressional review pursuant to the current procedures of the Regulatory Reform Act of 1996. In the event a party subsequently files a petition seeking an administrative review of whether a modification has, in fact, resulted in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard and the FDA denies the petition, the petitioner shall have the right to seek judicial review of the denial of the petition. In any judicial review, the deference accorded to the Agency's findings shall depend upon the extent to which the matter at issue is then within the Agency's field of expertise.

6. Manufacturing Oversight

The legislation would subject tobacco product manufacturers to good manufacturing practice standards ("GMPs") comparable to those applicable to medical device manufacturers, food companies and other FDA regulated industries, but tailored specifically to tobacco products. In this regard there would be:

-- Implementation of a quality control system (e.g., to prevent contamination)
-- Inspection of tobacco product materials (e.g., to ensure compliance with quality standards)
-- Requirements for proper handling of finished product
-- Tolerances for pesticide chemical residues in or on commodities in the possession of the manufacturer; existing EPA authority and oversight is retained

-- Inspection authority comparable to FDA's authority over other FDA regulated products, including the ability to enter manufacturing plants and demand certain records
-- Record keeping and reporting requirements

Tobacco farmers will face no greater regulatory burden than the producers of other raw products regulated by the federal government.

[Source/precedent: FDA Rule; FDCA, 21 U.S.C. Sections 346a; 360]

7. Access to Company Information

-- The Act would ensure that previously non-public or confidential the files of the tobacco industry - including internal documents - are disclosed to FDA, private litigants The details of the arrangement are set forth in documents from health research and the public. Appendix VI II.

-- Any subpoena authority FDA has with respect to manufacturers of medical devices generally would also apply to tobacco product manufacturers.

F. Non-tobacco Ingredients

Currently, at the federal level, tobacco manufacturers are required only to submit aggregated ingredient information (not by brand or company) to HHS for monitoring and review. Nor do tobacco products manufacturers currently disclose to consumers ingredients information for each of the tobacco products they sell.

The legislation would supersede the current often-criticized federal ingredient law and confirm FDA's authority to evaluate all additives in tobacco products. No non-tobacco ingredient could be used in manufacturing tobacco products unless the manufacturer can demonstrate that such ingredient is not harmful under the intended conditions of use. Further, the legislation would require the manufacturers to disclose to FDA the ingredients and the amounts thereof in each brand. In addition, it would require manufacturers to disclose ingredient information to the public under regulations comparable to what current federal law requires for food products, reflecting the intended conditions of use.

Under this proposed legislation:

-- Manufacturers would be required to provide FDA on a confidential basis a list of all ingredients, substances and compounds (other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco) which are added by the manufacturer to the tobacco, paper or filter of the tobacco product by brand and by quantity in each brand. For each such item, the manufacturer would identify whether or not it believes that the item would be exempt from public disclosure under the legislation.

-- Manufacturers would be required to submit, within 5 years of the enactment of the Act, for each ingredient currently added to the tobacco product, a safety assessment, based on the best available evidence, that there is a reasonable certainty in the minds of competent scientists that the ingredient (up to a

specified amount) is not harmful under the intended conditions of use. FDA shall promulgate applicable regulations within 12 months.

-- Within a statutory time assessment(s) in accordance within 90 days, FDA shall period FDA must review with the applicable standard; approve or disapprove an ingredient's safety, and if FDA takes no action, the ingredient is deemed approved. FDA may also challenge any manufacturer's assertion that an ingredient would be exempt from disclosure to consumers under applicable regulations comparable to what current federal law requires for food products.

-- New ingredients or use of current ingredients beyond the specified maximum amount are subject to a comparable process prior to use.

-- FDA would be required to protect as strictly confidential ingredient information not otherwise subject to public disclosure. If not subject to such disclosure, this information will be treated as trade secrets under federal law, exempt from FOIA requests and protected by procedures which shall include the designation of an agent who will store it in a locked cabinet, maintain a record of any person who has access to the information and require a written confidentiality commitment from any such person.

-- Manufacturers would be required to disclose to the public ingredients information pursuant to regulations comparable to what current federal law requires for food products. During an initial 5 year period, each ingredient that would be exempt from disclosure under the food regime would be presumed not to be subject to disclosure unless FDA disproves its safety. However, manufacturers would be required to disclose all ingredients which they have been compelled to publicly disclose with respect to a particular brand in order to comply with a statute or regulation (e.g., MA Ch 94 §307B).

-- Manufacturers would be required to have procedures for the selection, testing, purchase, storage and use of ingredients.

The Act would:

-Provide for record keeping regarding ingredients

-Allow FDA access to such records, with protection of proprietary information

[Source/precedent: MA Chapter 94, §307B; 21 C.F.R. §§101.4, 101.105, and 101.170; 18 U.S.C. §1905; 5 U.S.C. §552(b)(4); MA proposed reg. 105 C.M.R. §660.200(G)]

G. Compliance and Corporate Culture.

A key element in achieving the Act's goals will be forcing a fundamental change in the way the tobacco industry does business. Accordingly, the Act will provide for means to ensure that the industry will not only comply with the letter of the law but will also have powerful incentives to prevent underage usage of tobacco products and to strive to develop and market less hazardous tobacco products.

First manufacturers would be required to create plans, with an annual review and update, to:

-- Ensure compliance with all applicable laws and regulations

-- Identify ways to achieve the goals of reduced youth access to and incidence of underage consumption of tobacco products and provide internal incentives for doing so

-- Provide internal incentives to develop products with reduced risk

Second, with a special emphasis on laws and regulations that make it unlawful to sell tobacco products to underage persons and other laws directed at the issue of underage tobacco use, the manufacturers must implement compliance programs that include, at a minimum, the following elements:

-- Compliance standards and procedures to be followed by employees and agents that are reasonably capable of reducing the prospect of violations

-- Assignment to specific individual(s) within high-level personnel of the organization of overall responsibility to oversee compliance with the relevant standards and procedures, especially in regard to preventing underage tobacco use

-- Use of due care not to delegate substantial discretionary authority to individuals who the organization knows, or should have known through the exercise of due diligence, had a propensity to disregard corporate policy

-- Steps to communicate relevant standards and procedures to all employees and other agents (including lobbyists), e.g., by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required

-- Internal audits, hotlines and other measures to promote compliance

-- Appropriate disciplinary mechanisms and measures (e.g., discipline of employees who violate marketing restrictions)

-- Reasonable steps to respond appropriately to a violation and to prevent further similar violations

Furthermore, the Act would provide "whistleblowers" in the tobacco industry with the maximum protection available under current federal statutes.

Beyond compliance with the letter of the law, manufacturers would be required to take affirmative steps in furtherance of the spirit of the new regime, including:

-- Promulgating corporate principles that express and explain the company's commitment to compliance, reductions of underage tobacco use, and development of reduced risk tobacco products

-- Designating a specific individual within high-level personnel of the organization with appropriate responsibility and authority to promote efforts to attain these new standards

-- Providing reports to shareholders on compliance as well as progress toward meeting these new standards

Manufacturers would also be required to work with retail organizations on compliance, including retailer compliance checks and financial incentives for compliance.

Third, each tobacco manufacturer would require all contract lobbyists (and any other third-parties who may engage in lobbying activities on behalf of a manufacturer) to agree that they will not support or oppose any state or federal legislation, or seek or oppose any governmental action on any matter, without the manufacturer's express authorization. Manufacturers would also require anyone lobbying on their behalf to agree in writing that a) they are aware of and will fully comply with all applicable laws and regulations; b) they have reviewed and will fully comply with the Act as it applies to them; c) they have reviewed and will fully comply with the Consent Decree as it applies to them; and d) they have reviewed and will fully abide by the manufacturer's business conduct policies and any other policies and commitments as they apply, especially those related to prevention of youth tobacco usage.

Fourth, within ninety days after the Act's effective date, the Tobacco Institute

and the Council for Tobacco Research, U.S.A. would be dissolved and disbanded. Tobacco product manufacturers would be permitted to form new trade associations only in accordance with strict procedures and federal oversight designed to ensure compliance with antitrust and other applicable laws. (See Appendix IV)

Finally, companies would be subject to fines and penalties (including "Scarlet Letter" advertising) for breaching their obligations vis-a'-vis the development, implementation and enforcement of compliance plans and corporate principles. These penalties shall follow the scheme set forth in the Clean Air Act, up to $25,000 per day per violation with a total not to exceed $200,000. In addition, each manufacturer's employees shall be directed to report to that manufacturer's compliance officer any known or alleged violations of this Act by retailers or distributors. In accordance with procedures established by FDA, the compliance officer shall be required to furnish all such reports to FDA for reference to appropriate federal or state enforcement authorities. The manufacturer shall be subject to fines or penalties in the event its compliance officer fails to furnish any such reports to FDA.

[Source/precedent: Federal Organizational Sentencing Guidelines; various federal consent decrees; various corporate environmental programs]

H. Effective Dates

Many of the foregoing requirements relating to the reformation of the tobacco industry will become effective shortly after the Act is signed by the President; including the following categories of new rules, which will be implemented on the dates indicated:

Category / Effective Dates on Final Passage

Retail Product Displays / 9 months

Retail signage / 5 months

Advertising / 9 months

Package Labeling / 1/3 in 90 days

1/3 in 120 days

1/3 in 180 days

Sponsorships / 12/31/98

Vending machines / 12 months

Sampling / 3 months

GMPs / 24 months in accordance with rulemaking, whichever is later

Corporate compliance / 12 month

Face-to-face transactions / 3 months

Ban on sales of open packs / 3 months

20 cigarettes per pack minimum / 3 months

Puerto Rico pack size / 12 months

TITLE II: "Look Back" Provisions/State Enforcement incentives

A central aim of this legislation is to achieve dramatic and immediate reductions in the number of underage consumers of tobacco products. The legislation accordingly contains a "look-back" provision giving tobacco product manufacturers significant economic incentives to take every possible step to ensure that the advertising, marketing and distribution requirements of this Act are met, and imposing substantial surcharges on the manufacturers in the event that underage tobacco-use reduction targets are not achieved.

The "look-back" provision sets targets for the dramatic reduction of current levels of underage tobacco use (as measured by the University of Michigan's National High School Drug Use Survey "Monitoring the Future"). Underage use of cigarette products must decline by at least 30% from estimated levels over the last decade by the fifth year after the legislation takes effect, by at least 50% from estimated levels over the last decade by the seventh year after the legislation takes effect, by at least 60% from estimated levels over the last decade by the tenth year after the legislation takes effect, and remain at such reduced levels or below thereafter. (These required reductions amount to even steeper declines from current levels of underage smoking.) Underage use of smokeless tobacco products must decline by at least 25% from current levels by the fifth year after the legislation takes effect, by at least 35% from current levels by the seventh year after the legislation takes effect, by at least 45% from current levels by the tenth year after the legislation takes effect, and remain at such reduced levels or below thereafter. FDA will annually assess the

prevalence of underage tobacco use (based on the methodology employed by the University of Michigan survey) to determine whether these targets have been met.

If a target has not been met, FDA will impose a mandatory surcharge on the relevant industry (cigarette or smokeless tobacco) based upon an approximation of the present value of the profit the industry would earn over the lives of all underage users in excess of the target (subject to an annual cap of $2 billion for the cigarette industry (adjusted each year for inflation) and a comparably derived cap for the smokeless tobacco industry). Tobacco product manufacturers could receive a partial abatement of this surcharge (up to 75%) only if they could thereafter prove to FDA that they had fully complied with the Act, had taken all reasonably available measures to reduce youth tobacco use and had not taken any action to undermine the achievement of the required reductions.

A fuller description is provided in Appendix V.

In addition, the proposed Act goes well beyond the provisions of the Synar Amendment's "no tobacco sales to minors" law and related regulations, 42 U.S.C. § 300X-26, and the Final Rule promulgated thereunder, which became effective February 20,1996 (61 Fed. Reg., June 19,1996). The proposed Act requires the several States to undertake significant enforcement steps designed to dramatically reduce the incidence of youth smoking, and youth access to tobacco products. These enforcement obligations are funded by Industry Payments. Each state must maintain specific levels of enforcement effort, or the state risks the loss of a significant portion of the health care program funds otherwise payable to the state under the Act. Amounts withheld from states not doing an adequate enforcement job will be reallocated to states with a superior "no sales to minors" enforcement record. No state will be held responsible for sales to underage consumers outside that state's jurisdiction.

The details of these state enforcement incentives are set forth in Appendix VI.

TITLE III: Penalties and Enforcement; Consent Decrees; Non-Participating Companies

A. Penalties and Enforcement

-- This legislation will be enforceable both by the federal government, including FDA and civil and criminal divisions of the Department of Justice, and by the several States. FDA will also have the authority to contract directly with state agencies to assist with enforcement. If conduct is subject to a particular State's

consumer protection law or similar statute, such state may proceed under that law.

-- State enforcement actions - whether brought under the Act or a State's consumer protection law - could not impose obligations or requirements beyond those imposed by the legislation (except where the legislation does not specifically preempt additional state-law obligations), and would be limited to the civil and criminal penalties established by the legislation and by the prohibition on duplicative penalties. State enforcement proceedings under the Act (or predicated on conduct violating the Act), except those exclusively local in nature, would be removable to federal court. Nothing in the Act precludes a State from enforcing its laws in the ordinary fashion as to matters not covered by the Act or Protocol.

-- Civil and criminal penalties for violations of the legislation based on those governing other drugs or devices regulated under the Food, Drug and Cosmetic Act and, where applicable, under Title 18 of the U.S. Code.

-- In addition, the industry faces civil penalties of up to $10 million per violation for any violations of the obligations to disclose to the FDA research about tobacco-product health effects and information regarding the toxicity of non-tobacco ingredients and constituents used in their products. This penalty is ten times the largest penalty faced by other drug or device manufacturers for similar violations.

-- To reflect the fact that not all States have filed lawsuits against the tobacco industry, but that the intent of the negotiators is to provide the benefits of the settlement to all States, the industry also will enter into a binding and enforceable national tobacco control

Protocol embodying certain terms of the proposed resolution. As an enforceable contract, which would not be subject to facial constitutional challenge, this Protocol will provide benefits and enforcement rights to the federal government and all states.

B. Consent Decrees

-- Certain terms of the agreement will also be reiterated in consent decrees between the tobacco industry and the states that will not take effect until after enactment of the Act. These consent decrees will be identical to, and will reiterate, the terms of the agreement with respect to: (1) restrictions on advertising, marketing and youth access to tobacco products; (2) trade associations; (3) restrictions on lobbying; (4) disclosure of tobacco smoke

constituents; (5) disclosure of non-tobacco ingredients; (6) disclosure of existing and future industry documents relating to health, toxicity and addiction; (7) compliance and corporate culture; (8) obligations to make monetary payments to the States reflecting their reasonable share of the total provided by the Act; (9) obligations of the industry to deal only with distributors and retailers that operate in compliance with applicable provisions of law respecting the distribution, sale and marketing of tobacco products; (10) warnings, labeling and packaging (to the extent noted below); and (11) dismissal of other pending litigation specified by the parties.

-- The consent decrees will not contain provisions as to: (1) product design, performance or modification; (2) manufacturing standards and good manufacturing practices; (3) testing and regulation with respect to toxicity and ingredients approval; and (4) the national FDA "look back" provisions.

-- The consent decrees will provide that their terms are to be construed in conformity with the Act and the Protocol and with each other. State proceedings to enforce the provisions of the consent decrees may be brought in state court, subject to an acceptable procedure to ensure consistent rulings with respect to conduct that is not exclusively local in character. State proceedings to enforce the consent decrees may seek injunctive relief only, and may not seek criminal or monetary sanctions. A State shall not be limited from seeking criminal or other sanctions for a company's subsequent violation of an injunction entered by the court in an action brought to enforce the consent decree

-- The provisions of the consent decrees will remain enforceable regardless of whether subsequent changes in the Act or in any other provision of law diminish the obligations of the companies in the areas covered by the consent decrees, except: (1) where such changes create federal requirements that produce obligations in conflict with those contained in the consent decrees; (2) with respect to the allocation of funds; and (3) with respect to warnings, labeling and packaging. With respect to warnings, labeling and packaging, if the requirements of the Act are later modified, or if Congress subsequently prohibits warnings on tobacco products, the consent decrees will be modified to conform to such requirements. However, if Congress later eliminates altogether the warning requirement in the Act, the warnings originally set forth in the Act (the so-called Canadian warnings) shall be mandated and enforceable under the consent decrees.

-- In addition, the parties recognize that certain provisions of the consent decrees and the agreement may require them to act (or refrain from acting) in a manner that they might otherwise claim would violate the federal or state constitutions. They will therefore in the consent decrees expressly waive any

claim that the provisions of the consent decrees or the agreement violate the federal or state constitutions. The consent decrees will also state that if a provision of the Act covered by the decrees is subsequently declared unconstitutional, the provision remains an enforceable term of the consent decrees.

C. Non-participating companies

-- The regime envisioned by the resolution would be substantially undercut if certain companies were free to ignore the limitations it imposes, and were instead able to sell tobacco products at lower prices (because they were not making the payments described above) and through less restricted advertising and marketing activities. The resolution accordingly anticipates the possibility that some manufacturers of tobacco products may not consent to the institution of this regime. Rather than seeking to impose on such manufacturers the advertising restrictions, full required payments and corporate culture changes set forth above, the resolution avoids constitutional questions that might otherwise be raised by establishing a separate regime for non-participating manufacturers.

-- Non-participating manufacturers would be subject to the access restrictions and regulatory oversight set forth above. They would receive none of the civil liability protections described in Title VIII. Their product would be subject to a user fee equal to the portion of the payments by participating manufacturers allocated to fund public health programs and federal and state enforcement of the access restrictions.
-- The resolution further recognizes that - unlike the participating manufacturers - non-participating manufacturers will not have made consensual payments to settle governmental actions for health care costs, to settle class actions and in to provide consideration for the partial settlement of individual tort actions (including punitive damages claims). Because such actions would remain wholly unsatisfied, it is vital that the claimants be ensured that funds will be available to satisfy any judgments that may be obtained. Accordingly, the resolution requires that each nonparticipating manufacturer place into an escrowed reserve fund each year an amount equal to 150% of its share of the annual payment required of participating manufacturers (other than the portion allocated to public health programs and federal and state enforcement). These escrowed funds would be earmarked for potential liability payments, and the manufacturer would reclaim them with interest 35 years later to the extent they had not been paid out in liability.

-- Moreover, the resolution also recognizes that - because nonparticipating manufacturers are not subject to the corporate culture commitments requiring manufacturers to monitor distributor and retailer compliance with the underage

access restrictions -distribution and retail sales of those manufacturers' products present a particularly great obstacle to the achievement and enforcement of the access restrictions. Accordingly, the resolution provides that the exemption from civil liability applicable to distributors and retailers of the products of participating manufacturers will not apply to distributors and retailers who handle tobacco products of non-participating manufacturers.

Title IV: Nationwide Standards To Minimize Involuntary Exposure To Environmental Tobacco Smoke

Until now, there has been no minimum or other federal standard governing smoking in public places or at work. The legislation would:

-- Restrict indoor smoking in "public facilities" (i.e., any building regularly entered by 10 or more individuals at least one day per week) to ventilated areas with systems that:

- Exhaust the air directly to the outside;
- Maintain the smoking area at "negative pressure" compared with adjoining areas; and
- Do not recirculate the air inside the public facility.

-- Ensure that no employee shall be required to enter a designated smoking area while smoking is occurring. Cleaning and maintenance work in a designated smoking area shall be conducted while no smoking is occurring.
-- Exempt restaurants (but not "fast food" restaurants) ("Fast food" restaurant means any restaurant or chain of restaurants which primarily distributes food via customer pick-up (either at a counter or drive-through window). In addition, OSHA would be authorized to issue regulations clarifying this definition to the extent necessary to ensure that the intended inclusion of establishments catering largely to minors is achieved. Any such regulation may consider such factors as whether a restaurant either has attached playgrounds or play areas for children, uses ad campaigns that feature or prominently include cartoon characters and/or toy giveaways or advertises "happy meal" or other comparable kids-combination platters, and other factors OSHA deems relevant.) and bars (including those in hotels), private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants and prisons.
-- Direct OSHA to issue, not later than one year after the effective date of the legislation, regulations implementing and enforcing the preceding standards, with enforcement costs paid out of the Industry Payments. The smoking restrictions outlined in this Title would take effect on the first anniversary of the enactment of the legislation irrespective of whether the implementing regulations have been promulgated.

The legislation would not preempt or otherwise affect any other state or local law or regulation that restricts smoking in public facilities in an equal or stricter manner. Nor would the legislation preempt or otherwise affect any federal rules that restrict smoking in federal facilities.

[Source/precedent: H.R. 3434, as reported out of committee; WISHA workplace smoking rule; state law exemptions for the "hospitality sector"]

TITLE V: Scope and Effect

A. Scope of FDA Authority

-- All product sold in U.S. commerce
-- Covers new entrants; imports; U.S. duty free, etc.
-- BATF to retain fiscal authority over tobacco products
-- FTC to retain existing authority, except for "tar", nicotine, and carbon monoxide testing
-- Grower Limitation: FDA jurisdiction does not extend to the growing, cultivation or curing of raw tobacco (USDA has exclusive authority).

B. State Authority

1. Preservation of State and Local Government Laws and Legal Authority

-- While setting a federal "floor" for tobacco control measures in many substantive areas, this legislation preserves, to the maximum extent, state and local government authority to take additional tobacco control measures that further restrict or eliminate the product's use by and accessibility to minors.
-- This legislation also permits state and local governments to enact measures that further restrict or eliminate employee and general public exposure to smoking in workplaces and in other public and private places and facilities.
-- The legal authority of a state or local government to further regulate, restrict or eliminate the sale or distribution of tobacco products, and to impose state or local taxes on such products, also remains unchanged.
-- The legislation retains similar flexibility for Indian tribes, military facilities and other federal agencies.

2. Uniformity of Warning Labels, Packaging, Labeling and Other Advertising Requirements; Manufacturing Requirements
-- Current federal law providing for national uniformity of warning labels, packaging and labeling requirements, and advertising and promotion requirements related to tobacco and health, is preserved; except that this legislation gives FDA express authority to require changes in the language of the

warnings, subject to the standard requirement that it provide public notice and a hearing opportunity prior to making such changes.
-- Similarly, the provisions of FDCA designed to provide uniformity in product manufacturing and design requirements relating to medical devices will apply to tobacco products, except that any application by a State or locality for an exemption permitting it to adopt additional or different requirements relating to performance standards or good manufacturing practices may only be granted if the requirement would not unduly burden interstate commerce. Further, to ensure that FDA has an adequate opportunity to evaluate non-tobacco ingredients as described in Title 1(F), no exemption relating to ingredients may be applied for until the fifth anniversary of the effective date of the Act.

TITLE VI: Programs/Funding

TOTAL 25 YEAR PACKAGE FACE VALUE - $368.5 Billion

A. Up Front Commitment - Lump Sum Cash Payment - $10 Billion

1. Payable on Statute Signing Date.

B. Base Annual Payments - 25 Year Total Face Value is $358.5 Billion (Figures Subject to Inflation Protection and Volume Adjustments)

1. Duration - annual payments in perpetuity
2. Commencement - 12/31 of first full year after statute signing
3. Face Amounts (includes payments from all industry sources):
Year 1 2 3 4 5 6-8 9 after

Total Payments $8.5B $9.5B $11.5B $14B $15B $15B $15B $15B
Base Amount: $6B $7B $8B $10B $10B $12.5B $15B $15B
Public

Health Trust $2.5B $2.5B $3.5B $4B $5B $2.5B

4. Inflation Protection for Annual Payments

-- Greater of 3% or CPI applied each year on previous year, beginning with first annual payment.

5. Adjustment for Volume Decrease (Adult Volume Only) or Total Volume Increase

-- Beginning in year 1; payment made equal to scheduled annual payment times the ratio of actual relevant domestic tobacco product unit sales volume to

relevant base volume. In the event of a decline in volume, relevant actual volume and relevant base volume are adult volume figures; in the event of an increase in volume, relevant actual volume and relevant base volume are total volume figures. Base volume is 1996 volume.
-- Any reduction in an annual payment will be reduced by 25% of any increase above the industry's base year net operating profits (after application of inflator discussed above) from domestic sales of tobacco products.

6. Payment Protection

-- Provide for payment priority/continuation during bankruptcy/ reorganization proceedings. Protocol cannot be rejected in bankruptcy. Obligation for annual payments responsibility only of entities selling into domestic market

7. Pass-Through

-- In order to promote maximum reduction in youth smoking, the statute would provide for the Annual Payments to be reflected in the prices manufacturers charge for tobacco products.

C. Applicability

1. Applicable to All Sellers of Tobacco Products

-- Through protocol and statute to protocol signatories.
-- Through alternative statutory provisions to non-signatories.

D. Tax Treatment

All payments pursuant to this Agreement (including those pursuant to Title II) shall be deemed ordinary and necessary business expenses for the year of payment, and no part thereof is either in settlement of an actual or potential liability for a fine or penalty (civil or criminal) or the cost of a tangible or intangible asset.

TITLE VII: Public Health Funds From Tobacco Settlement As Recommended By The Attorneys General For Consideration By The President And The Congress

BASED ON THE PREMISE OF $1 BILLION FOR THE FIRST YEAR AND GRADUALLY INCREASING TO $1.5 BILLION THEREAFTER, ADJUSTED FOR INFLATION AFTER THE FIRST YEAR.

BASED ON THE PREMISE OF $1 BILLION FOR SMOKING CESSATION

FOR THE FIRST 4 YEARS AND $1 5 BILLION THEREAFTER, ADJUSTED FOR INFLATION.

(A) ALLOCATION OF GRANT MONIES AMONG PROGRAMS - The use of moneys under this Section shall be limited to programs established under this Section, shall be adjusted for inflation annually from the effective date, and shall be allocated among such programs as follows:

(1) $125,000,000 for the first three years and $225,000,000 annually thereafter to the Secretary of HHS to accomplish the purposes described in Paragraph (B) of this Section (Reduction in Tobacco Usage);
(2) $300,000,000 annually for the FDA to carry out its obligations under and to enforce the terms of this Act, including for grants to the states to assist in the enforcement of the provisions of the Act;
(3) $75,000,000 for the first two years, $100,000,000 in the third year, and $125,000,000 annually thereafter to fund state and local tobacco control community based efforts modeled on the ASSIST program, designed to encourage community involvement in reducing tobacco use and the enactment and implementation of policies designed to reduce the use of tobacco products;
(4) $100,000,000 annually to fund research and the development of methods for how to discourage individuals from starting to use tobacco and how to help individuals to quit using tobacco;
(5) Beginning in the second year, $75,000,000 annually for a period of ten (10) years to compensate events, teams or entries in such events, who lose sponsorship by the tobacco industry as a result of this Act, or who currently receive tobacco industry funding to sponsor events and elect to replace that funding, provided that the event, team, or entry is otherwise unable to replace its tobacco industry sponsorship during those given years. Funds used for this purpose shall promote a Quit Tobacco Use theme. After a ten year period, no additional funds shall be used for this purpose and the funds previously allocated to this purpose shall be used as follows: 50% to supplement funding of the multimedia campaigns in paragraph (1) of this subsection; 25% to supplement the funding of the enforcement provisions of paragraph (2) of this subsection; and 25% to supplement the funding of community action programs in paragraph (3) of this subsection.

(B) ESTABLISHMENT OF PROGRAMS BY THE SECRETARY - The Secretary shall establish programs to accomplish the following purposes---

(1) the reduction of tobacco product usage, both by seeking to discourage the initiation of tobacco use by persons under the age of 18 and by encouraging current tobacco users to quit through media-based and non-media based education, prevention and cessation campaigns. The Secretary may make grants

to state health departments to assist in carrying out the purposes of this provision.
(2) the research into and development and public dissemination of technologies and methods to reduce the risk of dependence and injury from tobacco product usage and exposure;
(3) the identification, testing and evaluation of the health effects of both tobacco and non-tobacco constituents of tobacco products;
(4) the promulgation of such other rules and regulations as are necessary and proper to carry out the provisions of this Act, as well as the development of such other programs as the Secretary determines are consistent with the goals of the Act.

(C) Public Education Campaign - $500,000,000 shall be spent annually in such multi-media campaigns designed to discourage and de-glamorize the use to tobacco products. To carry out such efforts, an independent non-profit organization with a Board made up of prestigious individuals and the leaders of the major public health organizations shall be created which shall contract or make grants to non-profit private entities who are unaffiliated with tobacco manufacturers or tobacco importers, who have a demonstrated record of working effectively to reduce tobacco product use and expertise in multi-media communications campaigns. The independent body shall be authorized to contract with state health departments, where appropriate, to run campaigns for their states and communities. In creating the program the Secretary or independent body shall also take into account the needs of particular populations. The goal shall be the reduction of tobacco product usage, both by seeking to discourage the initiation of tobacco use by persons under the age of 18 and by encouraging current tobacco users to quit.

(D) Tobacco Use Cessation - For the first 4 years, $1 billion, and thereafter, $1.5 billion of the total amount paid by the tobacco industry shall be paid into a Trust Fund to be used to assist individuals who want to quit using tobacco to do so.

Within 12 months the Secretary shall promulgate regulations to govern (1) the establishment of criteria for and a procedure for the approval of cessation programs and devices for which payment may be made under the program, (2) the eligibility requirements for individuals seeking to use moneys from the trust to fund the tobacco cessation efforts, and (3) the procedures to govern the tobacco cessation program.

The goal of the tobacco cessation program shall to enable the most tobacco users possible to receive assistance in their effort to quit using tobacco by providing financial assistance and identifying the programs, techniques, and

devices that have been shown to be safe and effective. Benefits to individuals should not be limited to a single effort, but should be tailored to the needs of individual smokers according to standards established by the Secretary using the best available scientific guidelines.

(E) Public Health Trust Fund Presidential Commission - A Presidential commission will be appointed to include representatives of the public health community, Attorneys General, Castano attorneys and others to determine the specific tobacco-related medical research for which the $25 Billion Public Health Trust Fund will be used.

TITLE VIII: Civil Liability

The following provisions would govern actions for civil liability related to tobacco and health.

A. General

1. Present Attorney General actions (or similar actions brought by or on behalf of any governmental entity), parens patriae and class actions are legislatively settled. No future prosecution of such actions. All "addiction"/dependence claims are settled and all other personal injury claims are reserved. As to signatory States, pending Congressional enactment, no stay applications will be made in pending actions, based upon the fact of this resolution, without mutual consent of the parties.
2. Third-party payor (and similar) actions pending as of 6/9/97 are not settled, but governed by provisions regarding past conduct set forth in Section B below.

B. Provisions as to Civil Liability for Past Conduct

The following provisions apply to suits for relief arising from past conduct - i.e., suits by persons claiming injury or damage caused by conduct taking place prior to the effective date of the Act.

1. All punitive damages claims resolved as part of overall settlement. No punitive damages in individual tort actions.
2. Individual trials only: i.e., no class actions, joinder, aggregations, consolidations, extrapolations or other devices to resolve cases other than on the basis of individual trials, without defendant's consent. Action removable by defendant to federal court upon receipt of application to, or order of, state court providing for trial or other procedure in violation of this provision.
3. Except as expressly provided in the Act, FCLAA and applicable case law unchanged by the Act.
4. Provided that the five negotiating companies enter into the Protocol: Protocol

manufacturers to enter into joint sharing agreement for civil liability. Protocol manufacturers not jointly and severally liable for liability of non-Protocol manufacturers. Trials involving both protocol and non-Protocol manufacturers to be severed.
5. Permissible parties:
Plaintiffs -
a. Claims of individuals, or claims derivative of such claims, must be brought either by person claiming injury or heirs.
b. Third-party payor (and similar) claims not based on subrogation that were pending as of 6/9/97.
c. Third-party payor (and similar) claims based on subrogation of individual claims; no extrapolations, etc.

Defendants
a. maintained only against companies, their assigns, any future fraudulent transferee, and/or entity for suit designated to survive defunct manufacturer. Actions may be manufacturing successors and
b. Manufacturers of agents agencies and liable vicariously for acts (including advertising attorneys).

6. No removal except under paragraph 2 above.

7. The development of "reduced risk" tobacco products after the effective date of the Act is neither admissible nor discoverable.

8. Statute of limitations: for all actions, individual state laws governing time periods from injury, discovery, notice or contamination/violation.

9. Annual aggregate cap for judgments/settlements: 33% of annual industry base payment (including any reductions for volume decline). If aggregate judgments/settlements for a year exceed annual aggregate cap, excess does not have to be paid that year and rolls over.

Any judgments/settlements run against defendant? but give rise to 80-cent-on-the-dollar credit against annual payment in year paid. Suitable provision for settlement consultation and permission. Manufacturers control insurance claims, and any insurance recovery obtained by manufacturers (net of cost) on account of judgment and/or settlement covered by above sharing arrangement allocated 80% to annual payments. Manufacturers retain any insurance proceeds on account of defense costs.

Provision with respect to individual judgments above $1 million: amount in excess of $1 million not paid that year unless every other judgment/settlement

can be satisfied within the annual aggregate cap. Excess rolls forward without interest and is paid at the rate of $1 million per year, until the first year that the annual aggregate cap is not exceeded (at which time the remainder is paid in full). For purposes of this provision, a third-party payor (or similar) action not based on subrogation is treated as having been brought by a single plaintiff and is subject to the $1 million rollover on that basis.

10. In the event that the annual aggregate cap is not reached in any year, a Commission appointed by the President will determine the appropriate allocation of the amount representing the unused amount of the credit. The Commission will be entitled to consider, among public health, governmental entities, and other uses of the funds, applications for compensation from persons, including nonsubrogation claims of third party payors, not otherwise entitled to compensation under the Act.

11. Defense costs paid by manufacturers.

C. Provisions as to Civil Liability for Future Conduct

The following provisions apply to suits for relief arising from future conduct - i.e., suits claiming injury or damage caused by conduct taking place after the effective date of the Act.

1. Paragraphs 2, 3, 5, 6, 7, 8, 9,10 and 11 in Section B apply.
2. No third-party payor (or similar) claims not based on subrogation.

TITLE IX: Board Approval

The terms of this resolution are subject to approval by the Boards of Directors of the participating tobacco companies.

Appendix I - Warnings in Advertisements

The space in press and poster advertisements for tobacco products that is to be devoted to the warning and, where relevant, the "tar," nicotine and any other constituent yield statements will be 20% of the area of the advertisement. The size of the printing of the warning and the yield statements shall be pro rata to the following examples:

a) Whole page broadsheet newspaper - 45 point type
b) Half page broadsheet newspaper - 39 point type
c) Whole page tabloid newspaper - 39 point type
d) Half page tabloid newspaper - 27 point type
e) DPS magazine - 31.5 point type

f) Whole page magazine - 31.5 point type
g) 28 cm X 3 columns - 22.5 point type
h) 20 cm X 2 columns - 15 point type

FDA may revise the required type sizes within the 20% requirement.

Appendix II - Retail Tobacco Product Seller Penalties

1. The sale of tobacco products to consumers by an unlicensed seller shall be a criminal violation, and be subject to minimum penalty of $1,000, or imprisonment, for 6 months, or both, if an individual, or in the case of a corporation, by a maximum penalty of $50,000. Any State or local jurisdiction may provide by statute or code more severe penalties.

2. In addition to any criminal penalties which may be imposed under any applicable state or local law, a tobacco product licensee may be subjected to civil sanctions, including penalties, or license suspension or revocation (on a site-by-site basis), or a combination thereof, for any violation of the provisions of the State licensing laws regarding sales to minors. Such sanction shall not exceed the following:
(a) For the first offense within any two year period, $500 or a 3 day license suspension or both.
(b) For the second offense within any two year period, $1,000 or a 7 day license suspension or both.
(c) For the third offense within any two year period, $2,000 or a 30 day license suspension or both.
(d) For the fourth offense within any two year period, $5,000 or a 6 month license suspension or both.
(e) For the fifth offense within any two year period, $10,000 or 1 year license suspension or both.
(f) For the sixth and any subsequent offenses within any two year period, $25,000 or a revocation of license with no possibility of reinstatement for a period of three years.
(g) Permanent license revocation is mandatory for the tenth offense within any two year period.

Each state must enact a statutory or regulatory enforcement scheme that provides substantially similar penalties to the minimum federal standards for a retail licensing program.

[Source/Precedent: Washington State Alcohol Licensing Act]

Appendix III - Application to Indian Tribes

A. Application Of Act

1. The provisions of the FDCA, the regulations of the FDA, and the Act relating to the manufacture, distribution and sale of tobacco products shall apply on Indian lands as defined in 18 U.S.C §1151 and on any other trust lands subject to the jurisdiction of an Indian tribe. To the extent that an Indian tribe engages in the manufacture, distribution or sale of tobacco products, the provisions of this Act shall apply to such tribe.

2. Any federal tax or fee imposed on the manufacture, distribution or sale of tobacco products shall be paid by any Indian tribe engaged in such activities, or by persons engaged in such activities on such Indian lands, to the same extent such tax or fee applies to other persons under the law.

B. Tribal Programs And Authority

1. For the purposes of the provisions of this Act, FDA is authorized to treat any federally-recognized Indian tribe as a state, and is authorized to provide any such tribe grant and contract assistance to carry out the licensing and enforcement functions provided by this section.

2. Such treatment shall be authorized only if:
(a) the Indian tribe has a governing body carrying out substantial governmental powers and duties;
(b) the functions to be exercised by the Indian tribe under this section pertain to activities on trust lands within the jurisdiction of the tribe; and
(c) the Indian tribe is reasonably expected to be capable of carrying out the functions required under this Act.

[Source/precedent: Clean Air Act, 42 U.S.C. §7601(d)]

3. FDA regulations which establish a retail licensing program shall apply on Indian trust lands, and each tribe's program shall be no less strict than the program of the State in which the tribe is located.

4. If FDA determines that an Indian tribe does not qualify for treatment as a state, FDA will directly administer the retailer licensing program, or may delegate such authority to the state.

C. Tobacco Compensation And Public Health Grants

1. A portion of the settlement funds to which a state is otherwise entitled shall be paid to HHS for distribution to the Indian tribes which have been certified by

FDA for treatment as states. The funds to be paid for such purposes on behalf of Indian tribes shall be determined by the proportion of registered tribal members resident on the reservation to the total population of the state in which the tribe is located. The funds to be distributed to Indian tribes shall be used for the same purposes as those funds are to be used by the states and be subject to the same compliance requirements for retail sales to minors as are the states under the Act.

2. The Department of Health and Human Services will annually pay to the governing body of each Indian tribe its share of the funds for use under an FDA-approved plan after annual certification by FDA, under the same standards that apply to the States, that the Indian tribe is in compliance with the requirements of the Act and any applicable regulations.

3. If HHS does not distribute all, or a portion, of an Indian tribe's share of the funds in any given year because the tribe has not qualified under the terms of this section or has not met the compliance requirements for retail sales to minors, those funds will be distributed to other qualified tribes in the same state for the same purposes and on the same proportional basis, less the non-qualified tribe's population, as other settlement funds are to be distributed to the tribes.

D. Obligations of Tobacco Manufacturers

1. Tobacco manufacturers shall not engage in any activity on Indian lands subject to this Act which activity the manufacturers may not otherwise do within a State.

2. Tobacco manufacturers also agree not to sell tobacco products for manufacture, distribution, or sale to an Indian tribe, or to a manufacturer, distributor, or retail seller subject to the jurisdiction of an Indian tribe, except under the same terms and conditions as the tobacco manufacturers impose under other manufacturers, distributors and retail sellers under the Act, or any applicable regulations.

Appendix IV - Industry Associations

Within 90 days of the effective date of the Act, the tobacco product manufacturers shall disband and dissolve the Council for Tobacco Research, U.S.A. and the Tobacco Institute. In addition, with respect to any new trade associations:

A. Tobacco product manufacturers may form or participate in any new tobacco industry trade association. Any such new trade association shall have an

independent board of directors, in accordance with the following requirements. For at least 10 years after the formation of the new association, a minimum of 20 percent of the directors, but at least one director, shall be other than a current or former director, officer or employee of any association member or affiliated company. No other director of a new trade association may be, at the same time, a director of any association member or affiliated company. The officers shall be appointed by the board and shall be employees of the association, and during their term shall not be employed by any association member or affiliated company. Legal counsel for any such association shall be independent and not serve as legal counsel to any association member or affiliated company while counsel to the association.

B. Any new tobacco product manufacturers' trade association shall adopt by-laws governing the association's procedures and the activities of its members, board, employees, agents and other representatives. The by-laws shall include, among other things, provisions that:

(1) members who are competitors in the tobacco industry shall not meet on the association's business except under sponsorship of the association;
(2) every board of directors meeting, board sub-committee meeting, general association or committee meeting, and any other association sponsored meeting, shall proceed under and strictly adhere to an agenda, approved by legal counsel and circulated in advance; and
(3) minutes describing the substance of the meetings shall be prepared for all such meetings, and shall be maintained by the association for a period of 5 years.

C. Moreover, under the new regime:

1. The structure, by-laws, and activities of tobacco industry trade associations shall be subject to continuing oversight by the U.S. Department of Justice and by state antitrust authorities. For a period of 10 years from the creation of a new trade association, such authorities may, without limitation on whatever other rights to access they may be permitted, upon reasonable prior notice:

(a) have access during regular office hours to inspect and copy all books, records, meeting agenda and minutes, and other association documents; and
(b) interview the association's directors, officers and employees, who may have counsel present.

The inspection and discovery rights provided in (a) and (b) above shall be exercised through a multi-state States' Attorneys General oversight committee. Any documents and information provided to any state pursuant to (a) and (b)

above shall be kept confidential by and among the states and shall be utilized only for governmental purposes of enforcing the Act and ancillary documents.

2. In order to achieve the goals of this Agreement and the Act relating to tobacco use by children and adolescents, the tobacco product manufacturers may, notwithstanding the provisions of the Sherman Act, the Clayton Act, or any other federal or state antitrust law, act unilaterally, or may jointly confer, coordinate or act in concert, for this limited purpose. Manufacturers must obtain prior approval from the Department of Justice of any plan or process for taking action pursuant to this section; however, no approval shall be required of specific actions taken in accordance with an approved plan. Approval or non-approval of a plan shall not be grounds for abatement of any surcharge to a manufacturer for failure to meet the reductions in underage tobacco use contemplated in this resolution and the Act.

Appendix V - "Look Back"

A summary of the "look-back" provision is as follows:

A. The Reduction Requirements.

1. The required reductions in underage tobacco use are measured against a base percentage. For underage use of cigarettes, the base percentage is the average weighted by relative population of such age groups in 1995 as determined by the U.S. Census Bureau, of (a) the average of the percentages of 12th graders (ages 16 and 17) from 1986 to 1996 who used cigarette products on a daily basis; (b) the average of the percentages of 10th graders (ages 14 and 15) from 1991 to 1996 who used cigarette products on a daily basis; and (c) the average of the percentages of 8th graders (age 13) from 1991 to 1996 who used cigarette products on a daily basis. The percentages are those measured by the University of Michigan's National High School Drug Use Survey "Monitoring the Future" or by such comparable index using identical methodology as is chosen by FDA after notice and hearing. For underage use of smokeless tobacco products, the base percentage is the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Census Bureau, of (a) the percentage of 12th graders (ages 16 and 17) in 1996 who used smokeless tobacco products on a daily basis; (b) the percentage of 10th graders (ages 14 and 15) in 1996 who used smokeless products on a daily basis; and (c) the percentage of 8th graders (age 13) in 1996 who used smokeless tobacco products on a daily basis. These percentages are to be derived from the same source as are the percentages with respect to use of cigarette products.

2. After the fifth year after enactment of the Act and annually thereafter, the

FDA will calculate the incidence of daily use of tobacco products by those under 18 years of age as follows:

For cigarette product use, the FDA will calculate the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Bureau of Census, of the percentages of 12th graders (ages 16 and 17), 10th graders (ages 14 and 15) and 8th graders (age 13) who used cigarette products on a daily basis during the preceding year. The percentages used in this calculation are to be those measured (a) by the University of Michigan Survey; or (b) by such comparable index using identical methodology as is chosen by the FDA after notice and hearing. If the methodology of the University of Michigan Survey is hereafter changed in a material manner from that employed in 1986-96 (including by changing the states or regions on which that Survey is based), the FDA shall use the percentages measured by an index chosen by it after notice and hearing having a methodology identical to that employed by the University of Michigan Survey in 1986-96.

For smokeless tobacco product use, the FDA will calculate the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Bureau of Census, of the percentages of 8th (age 13), 10th (ages 14 and 15) and 12^{th} graders (ages 16 and 17) who used smokeless tobacco products on a daily basis during the preceding year. This calculation is to be made using the same methodology as with respect to cigarette product use.

Any data underlying the University of Michigan Survey shall be available by request from FDA.

3. The reduction requirements (expressed as reduction from the base percentage) for cigarette products are as follows:

Year After Enactment Reduction Requirement

years 5-6: 30% reduction
years 7-9: 50% reduction
year 10: (and 60% reduction thereafter)

The reduction requirements (expressed as reduction from the base percentage) for smokeless tobacco products are as follows:

Year After Enactment Reduction Requirement

years 5-6: 25% reduction
years 7-9: 35% reduction
year 10 (and thereafter): 45% reduction

B. The Surcharge

Where the FDA's calculation (per the procedure set forth above) shows that the reduction requirements with respect to underage use of cigarette products were not met in the preceding year, the FDA will impose a surcharge on the manufacturers of cigarette products. Where the FDA's assessment shows that the Reduction Requirements with respect to underage use of smokeless tobacco products were not met in the preceding year, the FDA will impose a surcharge on the manufacturers of smokeless tobacco products.

1. The surcharge with respect to the cigarette industry will be calculated as follows:

(a) The FDA will the determine the percentage point difference between:

(i) the required percentage reduction applicable to a given year, and
(ii) the percentage by which the percent incidence of underage use of cigarette products for that year is less than the base incidence percentage. (In the event that the FDA's calculation of the percent incidence of underage use of cigarette products for that year is greater than the base incidence percentage, the number of percentage points used will be (i) the required percentage reduction for that year plus (ii) the percentage by which the actual percent incidence for that year is greater than the base incidence percentage.)

(b) The surcharge will be $80 million for each percentage point derived per the above procedure. This amount reflects an approximation of the present value of the profit the cigarette industry would earn over the life of underage smokers in excess of the required reduction (at current levels of population and profit). This calculation will be subject to the following:

(1) the $80 million will be adjusted proportionately for percentage increases or decreases compared with 1995 in the population of persons resident in the United States aged 13-17, inclusive.
(2) the $60 million will be adjusted proportionately for percentage increases or decreases compared with 1996 in the average profit per unit (measured in cents and weighted by annual sales) earned by the cigarette industry. (The average profit: per unit in 1996 will be derived from the industry's operating profit as reported to the SEC; and the average profit per unit for the year in which the surcharge is being determined will be calculated and certified to the FDA by a major, nationally recognized accounting firm having no existing connection to the tobacco industry using the same methodology as employed in deriving the average profit per unit for 1996.)

(3) the surcharge will be reduced to prevent double counting of persons whose smoking had already resulted in the imposition of a surcharge in previous years (to the extent that there were not underage smokers of comparable age in those previous years on whom a surcharge was not paid because of the cap set forth in paragraph (d) below).
(4) the surcharge may not exceed $2 billion in any year (as adjusted for inflation).

2. The surcharge with respect to the smokeless tobacco industry will be derived through a comparable procedure based upon a base per-percentage point amount and a cap specific to that industry.

3. The surcharge payable by cigarette manufacturers will be the joint and several obligation of those manufacturers, allocated by actual market share. The surcharge payable by smokeless tobacco product manufacturers will be the joint and several obligation of those manufacturers, as allocated in the same manner. Within each such respective product market, the FDA will make such allocations according to each manufacturer's relative market volume in the United States domestic cigarette or smokeless tobacco markets in the year for which the surcharge is being assessed, based on actual federal excise tax payments.

4. The surcharge for a given year, if any, will be assessed by the FDA by May I of the subsequent calendar year. Surcharge payments will be paid on or before July 1 of the year in which they are assessed by the FDA. The FDA may establish, by regulation, interest at a rate up (sentence incomplete)

5. After payment of its share of the surcharge, a tobacco product manufacturer may seek return of up to 75% of that payment through the abatement procedures described below.

C. Use of the Surcharge

The Surcharge funds would be used in an manner designed to speed the reduction of the levels of underage tobacco use. Upon final completion and review of any abatement petition, the FDA would transfer as grants to state and local government public health agencies, without further appropriation, 90% of all monies paid as Surcharge amounts. As a condition of such transfers, the recipients of the transferred funds would be required to spend them on additional efforts by state and local government agencies, or by contract between such agencies and private entities, to further reduce the use of tobacco products by children and adolescents. The FDA may retain up to 10 percent of such Surcharge amounts for Administrative Costs - the administration of the

Surcharge provisions of the Act and related proceedings, and for other administrative requirements imposed on the FDA by the Act. If 10 percent of the Surcharge amounts exceeds the Administrative Costs, the FDA may (1) transfer any portion of the excess to other federal agencies, or to state and local government agencies, to meet the objective of reduction of youth tobacco usage, or (2) may expend such amounts directly to speed the reduction of underage tobacco use.

D. Abatement Procedures

Upon payment of its allocable share of any Surcharge, a tobacco product manufacturer may petition the FDA for an abatement of the surcharge, and shall give timely written notice of such petition to the attorneys general of the several states.

1. The FDA shall conduct a hearing on an abatement petition pursuant to the procedures set forth in sections 554, 556 and 557 of Title 5 of the United States Code.

2. The attorneys general of the several states shall be entitled to be heard and to participate in such a hearing.

3. The burden shall be on the manufacturer to prove, by a preponderance of the evidence, that the manufacturer should be granted an abatement.

4. The FDA's decision on whether to grant an abatement, and the amount thereof, if any, shall be based on whether:

(a) The manufacturer has acted in good faith and in full compliance with the Act, and any FDA rules or regulations promulgated thereunder, and all applicable federal, state or local laws, rules or regulations;

(b) In addition to full compliance as set forth in (a) above, the manufacturer has pursued all reasonably available measures to attain the required reductions;

(c) There is evidence of any action, direct or indirect, taken by the manufacturer to undermine the achievement of the required reductions or other terms and objectives of the Act; and

(d) Any other relevant evidence.

5. Upon a finding by the FDA that the manufacturer meets the grounds for an abatement under the standards set forth above, it shall order an abatement of up to 75% of the Surcharge with interest at the average United States 52-Week

Treasury Bill rate for the period between payment and abatement of the surcharge. The FDA may consider all relevant evidence in determining what percentage to order abated.

6. Any manufacturer or state attorney general aggrieved by an abatement petition decision of the FDA may seek judicial review thereof within 30 days in the United States Court of Appeals for the District of Columbia Circuit. Unless otherwise specified in this Act, judicial review under this section shall be governed by sections 701-706 of Title 5 of the United States Code.

7. Notwithstanding the foregoing, a tobacco product manufacturer may neither file an abatement petition or seek judicial review of a decision denying an abatement if it has failed to pay the surcharge in a timely fashion.

8. No stay or other injunctive relief enjoining imposition and collection of the surcharge amounts pending appeal or otherwise may be granted by the FDA or any court.

[Source/precedent: 5 U.S.C. Sections 554, 556-57, 701-06]

Appendix VI: State Enforcement Incentives

The details of the state enforcement incentives are as follows:

In addition to FDA and other federal agency, state attorney general and 'other existing state and local law enforcement authority under current law, the proposed Act requires the following:

A. States must have in effect a "no sales to minors" law providing that it is unlawful for any manufacturer, retailer or distributor of tobacco products to sell or distribute any such products to any persons under the age of 18. (42 U.S.C. §300X-26(a)(1); 45 C.F.R. §96.130(b)). This state statutory requirement remains in addition to the federal regulatory prohibitions on retail sales of tobacco products to children and adolescents (also defined as persons under the age of 18) adopted by the FDA in its August 28, 1996 Final Rule (to be codified at 21 C.F.R. §897.14 et seq.);

B. States must conduct random, unannounced inspections at least monthly, and in communities geographically and statistically representative of the entire state and its youth population to ensure compliance with the "no sales to minors" law, and implement "any other action which the state believes are necessary to enforce the law." (goes further than 45 C.F.R. §96.130(c), 96.1 30(d)(1),(d)(2);

C. States must conduct at least 250 random, unannounced inspections of retailer

compliance with the "no sales to minors" law per year for each I million of resident population, as determined by the most recent decennial census. In the case of tribes, tribes must conduct no fewer than 25 such inspections per location of point of sale to consumers per year, conducted throughout the year.

Annual State Reporting Requirements

As a condition to receiving any moneys due and payable pursuant to the Act, States must annually submit a report to the FDA and the States must make their reports public (except as provided in (C) below) within the state. Such state reports must include at least the following:

A. A detailed description of enforcement activities undertaken by the state and its political subdivisions during the preceding federal fiscal year;

B. A detailed description of the state's progress in reducing the availability of tobacco products to individuals under the age of 18, including the detailed statistical results of the mandated compliance checks;

C. A detailed description of the methods used in the compliance checks, and in identifying outlets which were tested, with the FDA providing the state appropriate confidentiality safeguards for information provided to the agency regarding the timing and investigative techniques of state compliance checks that depend for their continued efficacy upon such confidentiality;

D. A detailed description of strategies the state intends to utilize in the current and succeeding years to make further progress on reducing the availability of tobacco products to children and adolescents; and

E. The identity of the "single state agency" responsible for fulfilling the Synar Amendment and the Act's requirements, including the coordination and report of state efforts to reduce youth access to tobacco products sold or offered for sale in the state. (strengthens and extends beyond 45 C.F.R. §96.130(e) by adding greater detail to the requirements and transferring reporting obligation of states to FDA from HHS)

Required Attainment Goals for State Enforcement

The FDA is required to make an annual determination, prior to allocating any moneys allocated to the states under the proposed Act for the purposes of defraying public health care program expenditures (but not including or conditioning moneys made available under the Act for the payment of private claims), as to whether each state has "pursued all reasonably available measures to enforce" the prohibition on sales of tobacco products to children and

adolescents.

In addition to the criteria set forth in 45 C.F.R. §96.130, the proposed Act will require the FDA to find presumptively that the state has not "pursued all reasonably available measures to enforce" the "no sales to minors law" unless the state has achieved, in the following years, the following compliance rate results for the retail compliance checks required by the Act:

Federal Fiscal Year Under Review	Retail Compliance Check Performance Target
5th Year after year of enactment of Act	75%
7th Year after year of enactment of Act	85%
10th Year after year of enactment of Act and annually thereafter	90%

These compliance percentages are expressed as the percentage of the random, unannounced compliance checks conducted pursuant to the Act for which the retailer refused sale of tobacco products to the potential underage purchaser. (note: these performance targets are far more stringent on the states than those in the Synar Amendment, which sets as a "final goal" a target of no less than 80% (i.e., an inspection failure rate of no more than 20%) within "several years. See 45 C.F.R. §96.130. In addition, the proposed Act's targets are mandatory, uniform national minimum performance requirements, while the Synar Amendment calls for HHS simply to "negotiate" an "interim performance target" beginning in 1998).

Reduction of Money Allocated to State Not Meeting Performance Targets

If a state does not meet the Act's "no sales to minors" performance targets for retail compliance checks, then the FDA may refuse to pay to that noncomplying state certain moneys otherwise payable to that state under the proposed Act. No state shall be held responsible for sales to underage consumers outside that state's jurisdiction. Specifically, the FDA may withhold from such state an amount equal to 1% of moneys otherwise payable to that state under the Act to defray health care expenditures of public programs of medical assistance for each percentage point by which the state's performance on its mandatory compliance checks fails to meet the required performance targets for that year. In no event may the FDA withhold more than 20% of the money otherwise

allocable to such state under the Act for such purposes.

The FDA shall reallot any Withhold Amounts, once final, to states that exceed the Act's Performance Targets, in amounts and by an allocation formula determined by the agency to reward those states with the best record of reducing youth access to tobacco products.

Appeal Following Withhold

Upon notice from the FDA of a withhold of moneys (the "Withhold Amount") allocable to the state under the Act, a state subject to such notice of withhold may petition the agency for a release and disbursement of the Withhold Amount, and shall give timely written notice of such petition to the attorney general for that state and to all tobacco product manufacturers. The agency shall hold, and invest in interest bearing securities of the United States government or its agencies, any Withhold Amounts subject to a pending petition for release and disbursement or related appeal until final disposition of such petition and appeal.

In the case of petition by a state for a release and disbursement of a Withhold Amount, the agency's decision on whether to grant such a petition, and the amount thereby released and disbursed, if any, shall be based on whether:

(1) the state has acted in good faith and in full compliance with the Act, and any agency rules or regulations promulgated thereunder;
(2) the state has pursued all reasonably available measures to attain the Retail Compliance Check Performance Targets and Youth Smoking Reduction Goals of the Act;
(3) there is evidence of any action, direct or indirect, taken by the state to undermine the achievement of the Retail Compliance Check Performance Targets and Youth Smoking Reduction Goals or other terms and objectives of the Act; and
(4) any other relevant evidence.

The burden shall be on the state to prove, by a preponderance of the evidence, that the state should be granted a release and disbursement of the Withhold Amount or any portion thereof. Prior to decision, the agency shall hold a hearing on the petition, with notice and opportunity to be heard given to the attorney general of that state and to all domestic tobacco product manufacturers.

Upon a finding by the agency that the state meets the grounds, as set forth above, and the burden of proof for a release and disbursement of a Withhold Amount, then it shall order a release and disbursement of up to 75% of the Withhold Amount appealed, and it shall so release and disburse to the state that

amount, with interest at the average United States 52-Week Treasury Bill rate for the period between notice and release of such Withhold Amount. The agency may consider all relevant evidence in determining that percentage of the Withhold Amount to order released and disbursed.

Any manufacturer or state attorney general aggrieved by a Withhold Amount decision of the agency may seek judicial review thereof within 30 days in the United States Court of Appeals for the District of Columbia Circuit. Unless otherwise specified in this Act, judicial review under this Section shall be governed by Sections 701-706 of Title 5 of the United States Code.

No stay or other injunctive relief enjoining imposition of the withhold pending appeal or otherwise may be granted by the FDA or any court.

No appeal may be taken from an agency decision denying a petition to release and disburse a Withhold Amount unless filed within 30 days following notice of such decision. No stay or other injunctive relief, enjoining imposition of the withhold pending appeal or otherwise, may be granted, by any court or administrative agency. Appeals filed hereunder shall be made to the District of Columbia Circuit Court of Appeals and, on appeal, shall be governed by the procedural and evidentiary provisions of the Administrative Procedures Act, unless otherwise specified in this Act. The judgment of the District of Columbia Court of Appeals on appeal shall be final.

Appendix VII - Restrictions on Point of Sale Advertising

The details with respect to point of sale advertising restrictions are as follows:

1. There shall be no Point of Sale Advertising of tobacco products, excluding adults-only stores and tobacco outlets, except as provided herein:

A. Each manufacturer of tobacco products may have not more than two separate point of sale advertisements in or at each location at which tobacco products are offered for sale, except any manufacturer with 25 percent of market share may have one additional point of sale advertisement. A retailer may have one sign for its own or its wholesaler's contracted house retailer or private label brand.

No supplier of tobacco products may enter into any arrangement with a retailer that limits the retailer's ability to display any form of advertising or promotional material originating with another supplier and permitted by law to be displayed at retail.

B. Point of Sale advertisements permitted herein each shall be of a display area not larger than 576 square inches (either individually or in the aggregate) and

shall consist of black letters on white background or recognized typographical marks.

Point of Sale advertisements shall not be attached to nor located within two feet of any fixture on which candy is displayed for sale. Display fixtures are permitted signs consisting of brand name and price, not larger than 2 inches in height.

2. Except as provided herein, Point of Sale Advertising shall mean all printed or graphical materials bearing the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco, which, when used for its intended purpose, can reasonably be anticipated to be seen by customers at a location at which tobacco products are offered for sale.

3. Audio and video formats otherwise permitted under the FDA Rule may be distributed to adult consumers at point of sale but may not be played or shown at point of sale (i.e., no "static video displays").

Appendix VIII - Public Disclosure of Past and Future Tobacco Industry Documents and Health Research

The legislation would ensure that previously non-public or confidential documents from the files of the tobacco industry -- including the results of internal health research -- are disclosed to the federal government, the States, public and private litigants, health officials and the public. The legislation also would provide for binding, streamlined and accelerated judicial determinations with nationwide effect in the event that disputes remain over the legitimacy of claims of privileges or protections, including attorney-client privilege, and work product and trade secret protections.

1. Under the Act, the manufacturers and CTR and TI would establish a national tobacco document depository that is open to the public and located in the Washington, DC area. This depository would serve as a resource for litigants, public health groups, and anyone else with an interest in the tobacco industry's corporate records on the subjects of smoking and health, addiction or nicotine dependency, safer or less hazardous cigarettes and underage tobacco use and marketing. Specifically:

-- The depository would include all of the documents produced to the other side by the manufacturers, CTR and TI in the Attorneys General actions (including all documents selected by plaintiffs from the Guilford, U.K. repository), Philip

Morris Companies Inc.'s defamation action against Capital Citis/ABC News, the FTC's investigation concerning Joe Camel and underage marketing, the *Haines* and *Cipollone* actions and the *Butler* action in Mississippi.

-- In the event there are additional existing documents discussing or referring to health research, addiction or dependency, safer/less hazardous cigarettes, studies of the smoking habits of minors and the relationship between advertising or promotion and youth smoking that the manufacturers or trade associations have not yet completed producing as agreed or required in the above actions, such additional documents shall be placed in the depository commencing within 90 days of the effective date of the Act, and concluding as soon as practicable thereafter.

-- Except for privileged and trade secret materials (which shall be exempt from disclosure into the depository), all documents placed in the depository shall be produced without any confidentiality designations of any kind.

-- Along with these document collections, the manufacturers and trade associations shall place into the depository all indices (as defined by the court's order in the Minnesota Attorney General action) of documents relating to smoking and health, including all indices identified by the manufacturers in the Washington, Texas and Minnesota Attorney General actions. Any computerized indices shall be produced in both a computerized and hard-copy form. (If reductions of any such indices are required in order to protect any privileged or trade secret information, such reductions shall be subject to the procedures set forth below for adjudicating any disputes over claims of privilege and trade secrecy.)

-- All documents placed into the depository shall be deemed produced for purposes of any litigation in the United States. The court in each underlying action shall retain the discretion to determine the admissibility on a case-by-case basis of any such produced document.

-- The tobacco industry shall bear the expense of maintaining the depository.

2. Immediately upon finalizing a resolution of these litigations with the Attorneys General, without waiting for Congress to embody these requirement in the proposed legislation, the manufacturers, CTR and TI shall:

-- Commence to conduct a good-faith, de novo, document-by-document review of all documents previously withheld from production in tobacco litigation on grounds of privilege. The purpose of this review shall be to identify documents which the reviewer concludes are not privileged. All documents so identified

shall be placed in the depository as soon as practicable.

-- Prepare and place in the national depository as soon as practicable a comprehensive new privilege log of all documents that the manufacturers, CTR and TI, based on their de novo review, continue to deem to be legitimately privileged against disclosure.

-- Itemize on this new privilege log all of the descriptive detail that the court has required defendants to furnish document-by-document on their privilege logs in the Minnesota Attorney General action, thereby ensuring that there will be sufficient detail on the privilege logs to enable any interested person to determine whether he or she wishes to challenge claims of privilege or trade secrecy on any particular documents.

3. The Act also would establish a panel of three federal Article Ill judges, appointed by the Judicial Conference, to hear and decide all disputes over claims of privilege or trade secrets, except for those disputes that already have been determined by other federal or state courts at the time the Act is enacted or are pending in cases prior to the time the Court has had an opportunity to begin to review privilege claims.

-- The three-judge panel shall decide all privilege or trade secrecy challenges asserted by the federal government, the States, public and private litigants, health officials and the public with respect to tobacco industry documents.

-- The Act would vest exclusive federal jurisdiction for the three-judge panel to decide any such disputes in accordance with the ABA/ALl Model Rules and/or principles of federal law with respect to privilege and the Uniform Trade Secrets Act with respect to trade secrecy. Any such adjudication shall be reviewable only in the manner prescribed by 28 U.S.C. [Sec. 1 25-certiorari].

-- The panel's adjudications shall be binding upon all federal and state courts in all litigation in the United States.

-- The panel shall be authorized to appoint Special Masters pursuant to Fed. R. Civ. P.53, with the cost to be borne by the tobacco industry.

-- Once the Act becomes effective and the three-judge panel is appointed, all disputes that may arise concerning privilege claims by the manufacturers or trade associations relating to smoking and health subjects must be resolved through this process, except for disputes in pending cases that can be resolved prior to the time the Court has had an opportunity to begin to renew privilege claims.

-- If a claim of privilege is not upheld, the three-judge panel shall consider whether the claimant had a good faith factual and legal basis for an assertion of privilege and, if the claimant did not, shall assess against the claimant costs and attorneys' fees and may assess such additional costs or sanctions as the panel may deem appropriate.

4. In order to expedite the process of judicial review and to ensure that the federal government, the States, public and private litigants, health officials and the public no longer need to be concerned that claims of privilege and trade secrecy are being asserted improperly or without legal basis, the legislation would create an accelerated process by which any public or private person or entity, subject to a right of intervention by any other interested person or entity, may challenge any claims of privilege or trade secrecy before the three- judge panel. Under the Act, a person or entity filing such an action to challenge to privilege or trade secrecy will not need to make any prima facie showing of any kind as a prerequisite to in camera review of the document or documents at issue.

5. The manufacturers would also be subject to certain continuing disclosure obligations over and above the aforementioned provisions and whatever further judicial discovery may be required in pending or future civil actions. Specifically, for the first time ever, the manufacturers would be required to disclose all original laboratory research relating to the health or safety of tobacco products, including, without limitation, all laboratory research relating to ways to make tobacco products less hazardous to consumers.

-- Whenever such research is performed in the future, the manufacturers shall disclose its results to the FDA.

-- In addition, all such research (except for legitimate trade secrets) shall be produced to the national document depository described above. In addition, the manufacturers and trade associations shall produce into the depository on an ongoing basis any future studies of the smoking habits of minors or documents discussing or referring to the relationship, if any, between advertising and promotion and underage smoking.

-- No original laboratory research relating to the health or safety of tobacco products shall be withheld from either the FDA or the depository on grounds of attorney/client privilege or work product protection.

6. The tobacco manufacturers' and CTR's and TI's compliance with any of the

provisions of this Act shall not be deemed a waiver of any applicable privilege or protection.

7. The Act will also incorporate reasonable and appropriate provisions to protect against the destruction of documents bearing on matters of public health or safety.

Appendix 6
ABC Expense Breakdown

Cost Estimates for Tobacco Enforcement Agents

	Per Agent Cost	Four Per Region (32)	
Salary Related Costs			
Base Salary*	$37,576	$1,202,432	Annual Costs
plus VRS	$4,073	$130,344	
plus SS	$2,330	$74,551	
plus Medicare	$545	$17,435	
plus HI credit	$256	$8,177	
plus Group Life	$271	$8,658	
plus HI premium	$3,312	$105,984	
Total Salary	$48,362	$1,547,580	
Training & Equipment			
Academy Training	$4,000	$128,000	One Time Costs
Car	$13,000	$416,000	
Radio	$7,000	$224,000	
Equipment	$2,500	$80,000	
Total Training & Equipment	$26,500	$848,000	
Other Related Expenses			
Program/Analytical Support**	$99,553		Annual Costs
plus VRS	$10,792		
plus SS	$6,172		
plus Medicare	$1,444		
plus HI credit	$677		
plus Group Life	$717		
plus HI premium	$6,624		
Total P/A Support	$125,978	$125,978	
Computer System Modification		$250,000	
Vehicle Expense (25,000 mile per agent@.$.20)		$160,000	
Public Relations Campaign		$40,000	
Miscellaneous Expenses (e.g. UAB buys)		$136,078	
Total Budget Request 1999		$3,107,636	
Total Budget Request 2000		$2,259,636	

* Weighted Average Grade 11 Step 10 (75% statewide, 25% NOVA)

** Three Program Support Tech (Grade 6 Step 10) and Agency Management Analyst Senior (Grade 10 Step 10)

Assessment of Agent Work Load

Current number of ABC licensed establishments	**13,000**
Current number of Special Agent positions	**110**
Number of ABC licensed establishments per agent	**118**
Estimated number of tobacco retailers	**15,000**
Estimated number of non-ABC licensed (30%)	**4,500**
Estimated Increase in Agents	**32**
Number of Establishments per Agent	**123**