

*Harold Clarke*

## KIDS DESERVE FREEDOM FROM TOBACCO ACT OF 1998

### "The KIDS Act"

#### Principles

Congress has an historic opportunity to enact legislation this year which will significantly reduce tobacco use -- especially among children. Nearly one in five deaths in America today is attributable to tobacco use, making it the single most preventable cause of premature death, disease and disability facing this country. These facts compel us to act now. However, to ensure the most effective result, legislation must embody the following principles:

- It must be bipartisan and comprehensive — not piecemeal — to ensure a fundamental and lasting change in the way tobacco products are marketed and sold in this country.
- It must attack the youth smoking epidemic as rapidly as possible by forcing the price of cigarettes to increase by \$1.50 per pack within the first two years, and providing for comparable increases in other tobacco products.
- It must preserve the rights of individuals and groups to sue tobacco manufacturers for the damages they have caused, while at the same time establishing a manageable framework to ensure timely payment of awards and settlements to claimants.
- It must provide incentives to states, local communities, schools, research institutions, health professionals and other stakeholders to develop innovative strategies to discourage youth smoking, and to assist adult smokers in kicking the habit.
- It must have as its primary purpose the promotion of aggressive anti-tobacco initiatives and public health improvements, including the provision of significant new resources for medical research.

#### Summary

The Kids Deserve Freedom from Tobacco Act of 1998 ("The KIDS Act") significantly improves upon and strengthens the June 1997 Attorneys General Tobacco Settlement Agreement ("June 1997 Tobacco Agreement"). The legislation would substantially reduce youth tobacco use through a comprehensive set of policy changes. These include increasing the cost of tobacco products, curtailing advertising and marketing to children, assuring appropriate industry oversight, expanding the availability of smoking cessation programs, and implementing a strong public health prevention and education strategy involving the private sector, schools, states and local communities.

#### ECONOMIC INCENTIVES

**Price Increase.** Public health experts agree that the single most important component of a comprehensive plan to reduce youth tobacco use is to significantly increase the price of tobacco products. Studies have shown that for every 10% increase in price, smoking is decreased at least 4% among adults and, more importantly, by at least 7% among children. Therefore, our proposal would **increase the price of a pack of cigarettes by \$1.50 within two years (\$1.00 the first year; \$0.50**

the second year). The price of other tobacco products — such as cigars and smokeless/spit tobacco — would be increased by a comparable amount. These increases would be achieved through **annual industry payments totaling \$20 billion the first year and \$25 billion per year thereafter** (indexed to inflation).

**Annual Youth Reduction Targets.** There is clear and abundant evidence that the tobacco industry has tailored its marketing and advertising programs to attract and encourage children to smoke. Largely because of the industry's success in this regard, 3,000 children start smoking every day in America. Accordingly, the KIDS Act would make the tobacco industry accountable for promoting and achieving a significant reduction in tobacco use among children. Our proposal would set an ambitious, but realistic schedule for **reducing the rate of youth smoking by 65 percent over the next ten years.**

The schedule would follow the recommendations of the **Final Report of the Advisory Committee on Tobacco Policy and Public Health**, chaired by Dr. C. Everett Koop and Dr. David Kessler. The following targets would be set:

| Year | Target | Year   | Target |
|------|--------|--------|--------|
| 2    | 15%    | 7      | 50%    |
| 3    | 20%    | 8      | 55%    |
| 4    | 25%    | 9      | 60%    |
| 5    | 30%    | 10     | 65%    |
| 6    | 40%    | Beyond | 65%    |

*(youth prevalence measured by monthly use)*

**Tough Look-back Penalties.** The KIDS Act would impose up to an additional \$10 billion per year in non tax-deductible penalties (indexed to inflation) on the tobacco industry for failure to meet these targets. Our penalty structure would impose stiff price increases if targets are not met, and unlike the June 1997 Tobacco Agreement or any other proposal, would impose charges on the companies that addict the most youth smokers.

First, **industry-wide penalties** would be assessed for failure to meet the above targets. Second, **company-specific penalties** would be imposed to prevent individual manufacturers from achieving any financial reward from addicting children to their products. Finally, unlike the June 1997 Tobacco Agreement, the KIDS Act would provide no abatement or rebate relief to tobacco companies.

- **Industry-wide Penalties:** Experts agree that to reduce youth consumption by one percentage point, an increase of at least \$.02 per pack is necessary. Therefore, for every percentage point missed in a given year, the KIDS Act would assess an industry-wide penalty of \$.02 per pack of cigarettes. For example, if the industry were to miss the target for a given year by 10 percentage points, the penalty assessed would be \$.20 per pack, or approximately \$4.8

billion. Furthermore, the KIDS Act would impose even tougher penalties on the tobacco industry for repeated failure to meet the targets: after two consecutive years of failure, it would double to \$.04 per pack for each percentage point missed; after four, it would triple to \$.06 per pack.

- **Company-specific Penalties:** The KIDS Act would impose the most hard-hitting assurance yet proposed that tobacco manufacturers reap no profit from recruiting and addicting children. The company-specific penalty for failure to meet the youth reduction target for a year would be \$1,500 for each teen smoker for which the individual company misses the target. The penalty structure is designed to make it several times more expensive for an individual company to addict a child to a lifetime of smoking, than to never have that child start smoking their brand in the first place.

**No Anti-trust Immunity.** Anti-trust laws are the most important safeguard we have against anti-competitive actions which hurt consumers and undermine the free market. As such, exceptions to these laws should be made only in rare circumstances, where important policy objectives outweigh the benefit of free market protections. The tobacco industry has not made a persuasive case for the grant of immunity it proposes. Therefore, unlike the June 1997 Tobacco Agreement, the KIDS Act would not extend any anti-trust exemptions to tobacco manufacturers.

**State Performance Bonus Payments.** The June 1997 Tobacco Agreement and pending legislative initiatives fail to provide strong economic incentives for states and communities to help decrease tobacco use among children. The KIDS Act would address this shortcoming by establishing a \$500 million annual "Performance Bonus Pool" for states that meet or exceed the reduction targets within their own borders.

This would serve as an important incentive for states and localities to develop aggressive and innovative anti-smoking strategies suited to their own individual needs. State-specific baselines and targets would be developed using a standardized methodology determined by the Centers for Disease Control and Prevention. Furthermore, the KIDS Act would clarify the authority of states and local governments to encourage the enactment of stronger anti-tobacco policies.

## II. CHANGING HOW TOBACCO PRODUCTS ARE SOLD

**Marketing and Advertising Reforms.** The tobacco industry spends an estimated \$5 billion per year on marketing and promotional activities — much of it targeted to children. The KIDS Act would fundamentally alter tobacco marketing and advertising practices to eliminate this reprehensible practice.

**Health Warning Labeling Reforms.** Evidence suggests that the current warning label regime for tobacco product packaging fails to adequately convey to children the risks associated with tobacco use. For example, nearly half of the 8th graders in a 1993 study denied any "great risk" associated with pack-a-day smoking, despite the presence of health warnings on tobacco product packaging. Moreover, consumer research indicates that alterations in format, composition and warning label content would make them far more effective in reaching children. Thus, the KIDS Act proposes to

significantly strengthen warning labels to improve their impact on the behavior of children. These messages would be regularly reviewed and updated by the Secretary of Health and Human Services to reflect changes in public awareness and attitudes about tobacco use.

**Minors' Access Reforms.** Illegal sales to minors and shoplifting are the primary means by which children obtain cigarettes and smokeless tobacco products. Estimates suggest that at least 516 million packs of cigarettes per year are consumed by minors, of which at least half are obtained through direct, illegal sales to minors. Shoplifting is another serious concern. In Iowa alone, more than 4 million packs of cigarettes are shoplifted every year.

The KIDS Act would address these problems by mandating that tobacco products be sold from behind store counters, banning vending machine sales, requiring retailers to verify age, and fining those vendors caught selling to minors. In addition, the KIDS Act would require states to license tobacco retailers and distributors to further ensure compliance with minors' access provisions. These reforms would build upon those developed by the U.S. Food and Drug Administration (FDA), and those contained in the June 1997 Tobacco Agreement.

Importantly, the tobacco companies would be bound by enforceable consent decrees to preclude them from challenging such restrictions in the courts, or from providing any means of support to third parties for this purpose.

**State Preemption.** The KIDS Act would clarify the authority of states and local governments to regulate the sale and use of tobacco products by repealing the preemption clause in existing federal law. However, it would preserve the national requirement for uniform packaging and labeling standards to ensure the free flow of interstate commerce.

### At-A-Glance: Changing How Tobacco Products are Sold

| Advertising                                                                                                                                                                                                                                                                               | Marketing                                                                                                                                                                                                                                                                                                                         | Labeling                                                                                                                                                                                                                        | Minors' Access                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>✓ B&amp;W text only (except in adult-only facilities and publications)</li> <li>✓ No human images or cartoon characters</li> <li>✓ No outdoor advertising</li> <li>✓ No advertising on the Internet</li> <li>✓ No self-service displays</li> </ul> | <ul style="list-style-type: none"> <li>✓ No "trinkets &amp; trash" (caps, jackets, bags, etc.) or proof-of-purchase clubs</li> <li>✓ No sponsorship of sporting events or other forms of entertainment</li> <li>✓ No paid product placement in movies, TV shows, on Internet or video games</li> <li>✓ No free samples</li> </ul> | <ul style="list-style-type: none"> <li>✓ Improved and updated warnings</li> <li>✓ Increased size</li> <li>✓ Rotating messages</li> <li>✓ Statements of intended use</li> <li>✓ Regularly reviewed and updated by HHS</li> </ul> | <ul style="list-style-type: none"> <li>✓ No distribution or sales to minors under age 18</li> <li>✓ Photo id required up to age 27</li> <li>✓ Face-to-face sales required</li> <li>✓ No single cigarettes sales</li> <li>✓ No vending machines sales</li> <li>✓ No self-service sales, except in adult-only establishments</li> </ul> |

### III. OVERSIGHT AND ENFORCEMENT

**FDA Authority.** Given the addictive, disease-causing nature of tobacco products, full and appropriate regulation is needed. Therefore, in addition to establishing new advertising and marketing restrictions, the KIDS Act would assure that FDA has the authority to effectively monitor and regulate the manufacture and distribution of tobacco products, promote the development of safer alternatives, and to conduct research. Importantly, FDA would not be required to overcome special burdens or procedural hurdles in its regulatory activities — a major flaw of the June 1997 Tobacco Agreement. The KIDS Act would classify "nicotine" as a drug, and "tobacco products" as Class II drug delivery devices (to include cigars, pipes and loose tobacco). In addition, our legislation would authorize FDA to implement a "reduction in risk" standard in its review of tobacco products.

The FDA's authority over tobacco products would be no more and no less than its authority over other drugs and devices. However, because of the addictive nature of tobacco products, and the high prevalence of their use, the KIDS Act would specifically prohibit the FDA from banning the sale of tobacco products to adults. Finally, the KIDS Act would ensure that FDA has adequate financial resources, and appropriate access to tobacco industry documents, to carry out its responsibilities.

***Ingredient Disclosure.*** Evidence strongly suggests that tobacco companies design and manufacture their products to satisfy and enhance nicotine dependence. Therefore, increased information about the role and function of tobacco additives is essential to the effective regulation of such products. The KIDS Act would substantially strengthen current ingredient disclosure requirements for tobacco manufacturers. For example, each company would be required, by brand and content, to submit lists of all tobacco additives. Further, if the Secretary of Health & Human Services determines that any of these additives pose a particular risk to smokers or others exposed to tobacco smoke, this information will be fully and promptly disclosed to the public.

***Reduced Risk.*** Much remains unknown about the feasibility and effectiveness of developing a less hazardous tobacco product. However, it is clear that tobacco manufacturers have the ability and knowledge to modify their products. Indeed, various forms of "reduced risk" nicotine delivery devices already have been introduced into the market. The KIDS Act would provide increased monitoring of new technologies and facilitate broad market availability of all innovations which effectively reduce the risk of tobacco use.

***Licensing.*** There are approximately one million tobacco outlets in the United States, and as recently as 1994, nearly three quarters sold tobacco products to minors. These include supermarkets, newsstands, hotels, gas stations, convenience stores, and other types of vendors. In light of the number and variety of such outlets, a tobacco retailer licensing program is critical to ending the illegal sale of tobacco products to minors. The KIDS Act would establish a state licensing program for retailers and distributors of tobacco products similar to the system now in place for alcoholic beverages. Additionally, tobacco manufacturers would be required to obtain federal licenses. These licenses could be revoked for noncompliance with state or federal law.

#### **IX. STOPPING CHILDREN FROM SMOKING BEFORE THEY START**

***Prevention in Communities and Schools.*** In addition to economic incentives, changes in tobacco product advertising and marketing, and improved oversight and enforcement, experts agree that a comprehensive slate of public health activities is needed to stop children from taking up this deadly habit. For example, research-tested school programs have proven to consistently and significantly reduce adolescent smoking. Therefore, the KIDS Act would provide \$1.4 billion to states for community and school-based prevention activities. These initiatives would be designed and implemented at the local level to ensure their effectiveness.

Because minority and low-income populations suffer a disproportionate burden of tobacco-related disease, and are among the greatest users of tobacco products, the KIDS Act would allocate a portion of the funding for community-based prevention activities to address their special needs.

***Counter Advertising.*** Research findings show that well-designed counter advertising initiatives do help to reduce teen smoking. Thus, an intensive, sustained media campaign at the state and federal level is needed to "deglamorize" tobacco use among young people. Accordingly, the KIDS Act would provide \$750 million annually to fund a nationwide campaign with national, state, and local components. Preeminent advertising firms with proven expertise in the formulation of messages aimed at children would be charged with the development and implementation of "deglamorization"

campaigns.

#### V. HELPING CURRENT SMOKERS KICK THE HABIT

**Smoking Cessation.** While the primary emphasis of our proposal is to reduce tobacco use among children, the more than 48 million adult Americans who currently smoke deserve and need help in kicking the habit. The KIDS Act would establish a coordinated federal and state-based initiative to increase access to, and awareness of, effective programs. When fully implemented, the legislation would provide \$1.5 billion annually for programs designed to enhance existing employer-based initiatives, and those which target uninsured and under-served populations.

#### VI. EXPANDING RESEARCH

**National Fund for Health Research.** Tobacco products kill more than 400,000 Americans every year — more deaths than from AIDS, alcohol and drug abuse, car accidents, murders, suicides, and fires combined. To stop this epidemic, we must strengthen our national commitment to finding preventive measures and cures for diseases — especially those related to tobacco use, including cancer, heart disease, emphysema and stroke. Therefore, the KIDS Act would establish a National Fund for Health Research to provide resources over and above those provided to the National Institutes of Health (NIH) in the annual appropriations process.

The KIDS Act would allot \$3.225 billion per year to the Fund. Each year, amounts within the Fund would be distributed to each of the NIH Institutes and Centers in accordance with the allocation formulas employed in the annual appropriations process. The KIDS Act would direct the Institutes and Centers receiving money from the Fund to give appropriate priority to tobacco-related research.

**Prevention and Cessation Research.** While we know a great deal about reducing tobacco use, much remains unknown. Therefore, a significant expansion of prevention and cessation research is critical to the success of any comprehensive effort to reduce tobacco use. In particular, more information is needed on why people use tobacco and on what program interventions are most effective. Efforts must also be undertaken to increase our understanding of the health effects of tobacco use and exposure to second-hand smoke. The KIDS Act would provide \$625 million per year for a major new research effort.

#### VII. HELPING THE VICTIMS OF TOBACCO-RELATED DISEASES

**Predictability for Tobacco Companies, Not Liability Concessions.** The KIDS Act would fully preserve the rights of individuals and groups to utilize the civil justice system to recover tobacco-related damages. Unlike the June 1997 Tobacco Agreement and some of the legislation currently pending in Congress, the KIDS Act would not ban class action lawsuits or punitive damage awards, as the tobacco industry has sought; simply put, it would provide no immunity to the tobacco industry. Given the industry's behavior, such liability protections cannot be justified or condoned.

However, to ensure the timely payment of awards and settlements to claimants, the KIDS Act would establish an annual cap on civil liability payments. This cap would not include payments made to states in settlement of existing Attorneys General suits, and would apply only to civil claims against past wrongdoing by the industry. **Our legislation would provide no protections from, or limitations on criminal prosecution of the tobacco industry.**

States which choose to accept funds under the KIDS Act would be required to discontinue their suits. In addition, the Castano Class Action lawsuits would be settled in return for the establishment of smoking cessation programs.

**National Victims' Compensation Fund.** To ensure that resources are readily available for the victims of tobacco-related diseases, the KIDS Act would provide for the establishment of a pre-funded National Victims' Compensation Fund (the "Fund"), from which court awards and settlements would be paid. Furthermore, given the uncertainty of the legal environment surrounding tobacco litigation, an additional Contingency Reserve Account would be established within the Fund. The Fund and the annual cap would be indexed to medical inflation.

- **Annual Base Payment:** At the beginning of each year, the tobacco industry would make a Base Payment of \$4 billion into the Fund; awards and settlements would be defrayed from this base amount. At the end of every year, any unobligated funds from the Base Payment would be deposited into an interest-bearing Contingency Reserve Account.
  - **Out-of-Pocket Supplement:** If awards and settlements exceed the Base Payment during any year, the industry would be liable for an additional \$4 billion in out-of-pocket payments to cover the excess.
  - **Contingency Reserve Account:** Any unobligated funds from the \$4 billion Base Payment would be placed in the Contingency Reserve Account (the "Account") within the Victims' Compensation Fund. For example, if awards and settlements paid in the first year amounted to \$1 billion, the remaining \$3 billion would be deposited into the Account. Funds in the Account would build up substantially in the early years as settlements and awards during this period are expected to be relatively small. For any year in which liability awards and settlements exceed \$4 billion, the Account would be drawn down to make the excess payments. In the unlikely event that awards and settlements ever deplete the Account in any year, unpaid claims would be rolled over and paid from the Base Payment at the beginning of the following year.
- If the Account accumulates a balance of \$20 billion, the Attorney General, in conjunction with the Secretary of Health & Human Services, would determine whether to continue to deposit excess funds therein, or to redirect those funds to anti-smoking and other public health activities authorized under the legislation.
- **Small Claimant Protection:** Under the KIDS Act, individuals and smaller classes of individuals would be given priority in disbursements from the Fund to ensure that large awards or settlements, paid to 3rd parties for example, would not deny smaller claimants timely payment of their claims.

## VIII. ENDING TOBACCO INDUSTRY SECRECY

For decades, to the severe detriment of the public health, the tobacco industry has concealed evidence of the consequences of tobacco use and deliberately misled the public. Moreover, tobacco manufacturers have broadly misused the doctrine of attorney-client privilege to cloak industry documents and research in a veil of secrecy. The KIDS Act would require tobacco companies and their agents -- as a precondition of eligibility for the annual cap on awards and settlements -- to waive attorney-client privilege for key documents relating to the health effects, safety, and marketing of their products to children. This reform would assist the victims of tobacco-related diseases in securing judgments against tobacco companies, and out-of-court settlements, without the traditional barriers and costs associated with document discovery.

As a further step to assure full disclosure of appropriate documents, the annual liability cap would not apply to any awards or settlements stemming from a case in which it is found that documents were not disclosed, as required under this Act, by the industry or a specific manufacturer.

**FDA to Obtain Needed Documents.** Tobacco companies would be required to turn over to the FDA all documents the agency deemed necessary to carry out its regulatory responsibilities -- including assessing the health effects of nicotine and other tobacco ingredients, the design and development of "less hazardous" or "safer" tobacco products, as well as the advertising, marketing and promotion of such products.

**Document Depository.** The establishment and administration of a document depository would be competitively awarded to a nongovernmental entity with no connections to the tobacco industry. Tobacco manufacturers and their agents would be required to submit all documents discovered through any litigation to this depository, along with an index in such form that would make the documents easily accessible and usable by plaintiffs and researchers.

## IX. TRANSITION ASSISTANCE TO FARMERS

Changes in national policy regarding tobacco products, and the expected decline in their consumption, will have ramifications for farming families, workers and communities in tobacco growing regions. The KIDS Act would provide \$15 billion for compensation, income support and transitional assistance to tobacco farming families, and for economic development and related assistance in tobacco-dependent communities.

## X. ASSURING CLEAN INDOOR AIR

Our knowledge is growing daily on the deleterious effects of exposure to Environmental Tobacco Smoke (ETS) in the home, the workplace and other public facilities. Annually, 3,000 Americans die of lung cancer caused by second-hand smoke, and 15,000 children under 18 months of age are hospitalized with respiratory infections related to ETS exposure.

Thus, the KIDS Act would provide strong protections for workers and the public against exposures to ETS. In addition, our bill would place significant emphasis on reducing ETS exposure in the

home -- including such measures as pediatric outreach, public service announcements, and comprehensive media campaigns.

The KIDS Act would also require Congress to comply with the "no smoking" policies already in place throughout the Executive Branch. Furthermore, legislation would not preempt states and local governments from establishing even more stringent policies to protect individuals from ETS.

#### **XI. STOPPING SMUGGLING AND SHOWING WORLD LEADERSHIP**

**Anti-Smuggling.** In some countries, significant increases in cigarette prices have resulted in large-scale smuggling operations. Contraband cigarette trafficking can occur both at national borders and between states with wide disparities in tobacco excise taxes. Since 1992, this criminal activity has increased by more than 500% in the United States.

As the price of cigarettes increases as a result of tobacco settlement legislation, actions must be taken to prevent the wide availability of contraband cigarettes. The KIDS Act would allocate \$300 million annually to strengthen federal anti-smuggling activities, both domestically and internationally. These measures would curtail the availability of "black market" tobacco products and ensure that economic and other policies aimed at reducing tobacco use have the chance to work.

**World Leadership.** The World Health Organization (WHO) currently estimates that tobacco use causes three million deaths per year worldwide — a number which is expected to increase exponentially as the U.S.-based tobacco industry intensifies its global marketing and promotional activities. By the year 2023, WHO projects tobacco-related mortalities will jump to ten million, with nearly 70 percent occurring in developing countries. This troubling trend is expected to accelerate with the enactment of strong anti-tobacco policies in the United States.

Unlike the June 1997 Tobacco Agreement, our bill would provide clear leadership on international efforts to curb tobacco use. The KIDS Act would terminate all support for tobacco promotion overseas by the United States Government, provide \$100 million per year to fund global education efforts, and encourage America's participation with other nations in efforts to harmonize tobacco policies worldwide.

#### **XII. INDUSTRY CONSENT DECREES**

Voluntary, but legally-binding consent decrees — signed by federal and state governments and tobacco manufacturers — are critical to the success of any comprehensive tobacco legislation aimed at significantly reducing tobacco use by children. Without these decrees, key provisions of such a law could be delayed by lengthy legal challenges. To help avoid this problem, the KIDS Act would require tobacco companies to sign legally-binding consent decrees in order to receive the benefits of the annual liability cap established under the legislation. Violation of any of the terms of the consent decrees would result in exclusion of that company from the annual liability cap. Among other things, the consent decrees — which would be enforceable by the U.S. Attorney General or State Attorneys General through federal and state courts — would commit the companies to abide

by the following agreements:

- Not to directly or indirectly bring or support legal challenges to the implementation of any aspect of the KIDS Act, including existing or future FDA regulatory authority, document disclosure, youth look-back survey methodology and penalties, and advertising and marketing restrictions;
- To pay and fully pass through the cost of annual industry payments and look-back penalties, assuring that the price of cigarettes would increase by at least \$1.50 per pack over 2 years, with comparable increases for other tobacco products;
- All reforms related to the labeling, sale, advertising and promotion of tobacco products intended by this Act;
- Not to directly, or through contractors, lobby federal, state or local governments against any provision of this Act;
- To only do business with those retailers and distributors in full compliance with all provisions of this Act;
- To dissolve the Tobacco Institute and other existing trade associations;
- Not to advertise over the Internet; and,
- To comply also with all of the marketing and advertising restrictions in both the FDA regulation and the proposed June 1997 Tobacco Agreement.

### **XIII. ANNUAL TOBACCO PAYMENTS AND SPENDING**

**Industry Payments:** The KIDS Act would require a non-deductible industry payment of \$10 billion immediately upon enactment. That payment would be used by states and local communities, as well as the federal government, to begin implementation of the strong anti-tobacco measures authorized under the Act.

One year after enactment, the tobacco industry would make a payment of \$20 billion to the National Tobacco Trust Fund. Each year thereafter, the industry payment would be \$25 billion, indexed to inflation.

**Payments to States:** As under the June 1997 Tobacco Agreement, \$193.5 billion over 25 years would be reserved for state use. Of those funds, 50% would be distributed to states to use for improving early education, child care, or other purposes at their discretion. The remaining 50% would be allocated to the states for the purposes of tobacco prevention, education, and cessation, and for the expansion of existing public health or children's health programs.

Additionally, \$500 million per year would be awarded from the Performance Bonus Pool to states

which meet or exceed their Annual Youth Reduction Targets.

***Payments for National Efforts:*** Under the KIDS Act, \$4 billion of the industry's yearly payment would be directed to the National Victims' Compensation Fund as the Annual Base Payment. Remaining industry payments would be used exclusively for national anti-tobacco and public health purposes.

# KIDS DESERVE FREEDOM FROM TOBACCO ACT OF 1998

## "The KIDS Act"

### At-A-Glance

*Bill  
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|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Increase Cigarettes by \$1.50 Per Pack in 2 Years</b> | The KIDS Act would increase the price of a pack of cigarettes by \$1.50 within 2 years: by \$1.00 per pack the first year, and by an additional \$0.50 the second year. The price of other tobacco products would be increased by a comparable amount. These increases would be achieved through annual industry payments totaling \$20 billion the first year and \$25 billion per year thereafter (indexed to inflation).                                      |
| <b>Aggressive and Escalating Look-Back Penalties</b>     | Based on recommendations made by the Koop-Kessler Advisory Look-Back Penalties Committee, the KIDS Act is designed to reduce youth smoking by at least 65% over the next ten years. Both industry-wide and company-specific penalties for failure to achieve targeted reductions in youth smoking would be assessed. These penalties could add an additional \$10 billion per year to industry payments. Furthermore, all penalties would be non tax-deductible. |
| <b>State Bonus Pool</b>                                  | The KIDS Act is the only proposal designed to reward states that meet or exceed state-specific youth reduction targets. A "performance bonus pool" would be established as an economic incentive for states and localities to develop aggressive and innovative anti-smoking strategies suited to their own individual needs and populations.                                                                                                                    |
| <b>Significant Marketing and Advertising Reforms</b>     | The KIDS Act would fundamentally alter tobacco marketing and advertising practices to eliminate promotional activities aimed at children. Provisions in the Act would build on the FDA rule by adding the advertising and marketing restrictions included in the proposed June 1997 Tobacco Agreement.                                                                                                                                                           |
| <b>Full FDA Authority</b>                                | The KIDS Act would affirm the FDA's authority over tobacco products -- without any of the procedural constraints proposed by the June 1997 Tobacco Agreement. The bill would classify nicotine as a drug and tobacco products as drug delivery devices, and allow FDA to implement a "public health" standard in its review of tobacco products.                                                                                                                 |
| <b>Comprehensive Prevention and Cessation Efforts</b>    | The KIDS Act would fund a comprehensive slate of public health activities to reduce tobacco use and promote cessation, including school-based activities and an intensive, sustained media campaign to "deglamorize" tobacco use among young people. Many of these initiatives would be designed and implemented at the local level to ensure responsiveness to each community's needs.                                                                          |

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|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Expanded Health Research</b>                                 | The KIDS Act would strengthen research aimed at identifying and developing the most effective tobacco prevention and cessation strategies possible. Moreover, it would provide for a significant expansion of medical research.                                                                                                                                                                                                                                                                                                                       |
| <b>Timely Payment of Awards and Settlements</b>                 | <p>To ensure that resources are readily available for the victims of tobacco-related diseases, the KIDS Act would establish a pre-funded National Victims' Compensation Fund from which court awards and settlements would be paid. Annual industry payments to the Fund would be capped at \$8 billion. This cap would apply only to civil claims against past wrongdoing by the industry.</p> <p>The Kids Act would fully preserve the rights of individuals and groups to utilize the civil justice system to recover tobacco-related damages.</p> |
| <b>Settlement of State Suits and Castano Class Action Suits</b> | The KIDS Act would give states the opportunity to settle their suits in exchange for funding from the National Tobacco Trust Fund established under this Act. In addition, the Castano Class Action lawsuits would be settled in return for the establishment of smoking cessation programs.                                                                                                                                                                                                                                                          |
| <b>Tough Document Disclosure Requirements</b>                   | The KIDS Act would require tobacco manufacturers and their agents to disclose all previously non-public, internal documents relating to the health effects, safety, and marketing of their products to children. As a precondition of eligibility for the annual cap on awards and settlements, tobacco companies would be required to waive attorney-client privilege on key documents.                                                                                                                                                              |
| <b>Reducing Exposure to Environment Tobacco Smoke (ETS)</b>     | The KIDS Act would provide strong protections for workers and the public against exposure to ETS. In addition, our bill would place significant emphasis on reducing ETS exposure in the home through such measures as pediatric outreach, public service announcements, and a comprehensive media campaign.                                                                                                                                                                                                                                          |
| <b>International Leadership</b>                                 | The KIDS Act would provide clear leadership on international efforts to reduce tobacco use. This proposal would end U.S. Government support for tobacco promotion overseas, fund global education and anti-smuggling initiatives, and encourage our participation with other nations in efforts to strengthen tobacco policies worldwide.                                                                                                                                                                                                             |
| <b>Assistance for Tobacco Farming Communities</b>               | The KIDS Act would provide funding for transitional assistance to tobacco farming families, and for economic development and related assistance to tobacco-dependent communities.                                                                                                                                                                                                                                                                                                                                                                     |

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## "The KIDS Act"

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### Principles

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- It must be bipartisan and comprehensive — not piecemeal — to ensure a fundamental and lasting change in the way tobacco products are marketed and sold in this country.
- It must attack the youth smoking epidemic as rapidly as possible by forcing the price of cigarettes to increase by \$1.50 per pack within the first two years, and providing for comparable increases in other tobacco products.
- It must preserve the rights of individuals and groups to sue tobacco manufacturers for the damages they have caused, while at the same time establishing a framework to ensure that funds are available to cover awards and settlements secured by successful claimants.
- It must provide incentives to states, local communities, schools, research institutions, health professionals and other stakeholders to develop innovative strategies to discourage youth smoking, and to assist adult smokers in kicking the habit.
- It must have as its primary purpose the promotion of aggressive anti-tobacco initiatives and public health improvements, including the provision of significant new resources for medical research.

### Summary

The KIDS DESERVE FREEDOM FROM TOBACCO ACT OF 1998 ("The KIDS Act") significantly improves upon and strengthens the June 1997 Attorneys General Tobacco Settlement Agreement ("June 1997 Tobacco Agreement"). The legislation would substantially reduce youth tobacco use through a comprehensive set of policy changes. These include increasing the cost of tobacco products, curtailing advertising and marketing to children, assuring appropriate industry oversight, expanding the availability of smoking cessation programs, and implementing a strong public health prevention and education strategy involving the private sector, schools, states and local communities.

### I. ECONOMIC INCENTIVES

**Price Increase.** Public health experts agree that the single most important component of a comprehensive plan to reduce youth tobacco use is to significantly increase the price of tobacco products. Studies have shown that for every 10% increase in price, smoking is decreased at least 4% among adults and, more importantly, at least 7% among children. Therefore, our proposal would **increase the price of a pack of cigarettes by \$1.50 within two years** (\$1.00 the first year; \$0.50 the second year). The price of other tobacco products — such as cigars and smokeless/spit tobacco — would be increased by a comparable amount. These increases would be achieved through **annual industry payments totaling \$20 billion the first year and \$25 billion per year thereafter** (indexed to

payments totaling \$20 billion the first year and \$25 billion per year thereafter (indexed to inflation).

**Annual Youth Reduction Targets.** There is clear and abundant evidence that the tobacco industry has tailored its marketing and advertising programs to attract and encourage children to smoke. Largely because of the industry's success in this regard, 3,000 children start smoking every day in America. Accordingly, the KIDS Act would make the tobacco industry accountable for promoting and achieving a significant reduction in tobacco use among children. Our proposal would set an ambitious, but realistic schedule for **reducing the rate of youth smoking by 65 percent over the next ten years.**

The schedule would follow the recommendations of the **Final Report of the Advisory Committee on Tobacco Policy and Public Health**, chaired by Dr. C. Everett Koop and Dr. David Kessler. The following targets would be set:

| YEAR | REDUCTION | YEAR   | REDUCTION |
|------|-----------|--------|-----------|
| 2    | 15%       | 7      | 50%       |
| 3    | 20%       | 8      | 55%       |
| 4    | 25%       | 9      | 60%       |
| 5    | 30%       | 10     | 65%       |
| 6    | 40%       | Beyond | 65%       |

(youth prevalence measured by monthly use)

**Tough Look-back Penalties.** The KIDS Act would impose up to an additional \$10 billion per year in non tax-deductible penalties (indexed to inflation) on the tobacco industry for failure to meet these targets. Our penalty structure would impose stiff price increases if targets are not met, and unlike the June 1997 Tobacco Agreement or any other proposal, is structured to impose disproportionate penalties on the companies that addict the most youth smokers.

First, **industry-wide penalties** would be assessed for failure to meet the above targets. Second, **company-specific penalties** would be imposed to prevent individual manufacturers from achieving any financial reward from addicting children to their products. Finally, unlike the June 1997 Tobacco Agreement, the KIDS Act would provide no abatement or rebate relief to tobacco companies.

-- **Industry-wide Penalties:** Experts agree that to reduce youth consumption by one percentage point, a non tax-deductible penalty of at least \$.02 per pack is necessary. Therefore, for every percentage point missed in a given year, the KIDS Act would assess an industry-wide penalty of \$.02 per pack of cigarettes. For example, if the industry were to miss the target for a given year by 10 percentage points, the penalty assessed would be \$.20 per pack, or approximately \$4.8 billion. Furthermore, the KIDS Act would impose even tougher penalties on the tobacco industry for repeated failure to meet the targets: after two consecutive years of failure, it would double to \$.04 per pack for each percentage point missed; after four, it would triple to \$.06 per pack.

-- **Company-specific Penalties:** The KIDS Act would impose the most hard-hitting assurance yet proposed that tobacco manufacturers reap no profit from recruiting and addicting children. The company-specific penalty for failure to meet the youth reduction target for a year would be \$1,500 for each teen smoker for which the individual company misses the target. As with the industry-wide penalties, the KIDS Act would impose even tougher penalties on individual tobacco companies for repeated failure to meet these targets. After two consecutive years of failure, the penalty would double to \$3,000 for each teen smoker for which the individual company misses the target. The penalty structure is designed to make it several times more expensive for an individual company to addict a child to a

designed to make it several times more expensive for an individual company to addict a child to a lifetime of smoking, than to never have that child start smoking its product in the first place.

**No Anti-trust Immunity.** Anti-trust laws are the most important safeguard we have against anti-competitive actions which hurt consumers and undermine the free market. As such, exceptions to these laws should be made only in rare circumstances, where important policy objectives outweigh the benefit of free market protections. The tobacco industry has not made a persuasive case for the granting the immunity it proposes. Therefore, unlike the June 1997 Tobacco Agreement, the KIDS Act would not extend any anti-trust exemptions to tobacco manufacturers.

**State Performance Bonus Payments.** The June 1997 Tobacco Agreement and pending legislative initiatives fail to provide strong economic incentives for states and communities to help decrease tobacco use among children. The KIDS Act would address this shortcoming by establishing a \$500 million annual "Performance Bonus Pool" for states that meet or exceed the reduction targets within their own borders.

This would serve as an important incentive for states and localities to develop aggressive and innovative anti-smoking strategies suited to their own individual needs. State-specific baselines and targets would be developed using a standardized methodology determined by the Centers for Disease Control and Prevention. Furthermore, the KIDS Act would clarify the authority of states and local governments to encourage the enactment of stronger anti-tobacco policies.

## II. CHANGING HOW TOBACCO PRODUCTS ARE SOLD

**Marketing and Advertising Reforms.** The tobacco industry spends an estimated \$5 billion per year on marketing and promotional activities — much of it targeted to children. The KIDS Act would fundamentally alter tobacco marketing and advertising practices to eliminate this reprehensible practice.

**Health Warning Labeling Reforms.** Evidence suggests that the current warning label regime for tobacco product packaging fails to adequately convey to children the risks associated with tobacco use. For example, nearly half of the 8th graders in a 1993 study denied any "great risk" associated with pack-a-day smoking, despite the presence of health warnings on tobacco product packaging. Moreover, consumer research indicates that alterations in format, composition and warning label content would make them far more effective in reaching children. Thus, the KIDS Act proposes to significantly strengthen warning labels to improve their impact on the behavior of children. These messages would be regularly reviewed and updated by the Secretary of Health and Human Services to reflect changes in public awareness and attitudes about tobacco use.

**Minors' Access Reforms.** Illegal sales to minors and shoplifting are the primary means by which children obtain cigarettes and smokeless tobacco products. Estimates suggest that at least 516 million packs of cigarettes per year are consumed by minors, of which at least half are obtained through direct, illegal sales to minors. Shoplifting is another serious concern. In Iowa alone, more than 4 million packs of cigarettes are shoplifted every year.

The KIDS Act would address these problems by mandating that tobacco products be sold from behind store counters, banning vending machine sales, requiring retailers to verify age, and fining those vendors caught selling to minors. In addition, the KIDS Act would require states to license tobacco retailers and distributors to further ensure compliance with minors' access provisions. These reforms would build upon those developed by the U.S. Food and Drug Administration (FDA), and those contained in the June 1997 Tobacco Agreement.

Importantly, the tobacco companies would be bound by enforceable consent decrees to preclude them from challenging such restrictions in the courts, or from providing any means of support to third parties for this purpose.

**State Preemption.** The KIDS Act would clarify the authority of states and local governments to regulate the sale and use of tobacco products by repealing the preemption clause in existing federal law. However, it would preserve the national requirement for uniform packaging and labeling standards to ensure the free flow of interstate commerce.

#### At-A-Glance: Changing How Tobacco Products are Sold

| Advertising                                                      | Marketing                                                                    | Labeling                              | Minors' Access                                             |
|------------------------------------------------------------------|------------------------------------------------------------------------------|---------------------------------------|------------------------------------------------------------|
| B&W text only (except in adult-only facilities and publications) | No "trinkets & trash" (caps, jackets, bags, etc.) or proof-of-purchase clubs | Improved and updated warnings         | No distribution or sales to minors under age 18            |
| No human images or cartoon characters                            | No sponsorship of sporting events or other forms of entertainment            | Increased Size                        | Photo id required up to age 27                             |
| No outdoor advertising                                           | No paid product placement in movies, TV shows, on Internet or video games    | Rotating Messages                     | Face-to-face sales required                                |
| No advertising on the Internet                                   | No free samples                                                              | Statements of intended use            | No single cigarettes sales                                 |
| No self-service displays                                         |                                                                              | Regularly reviewed and updated by HHS | No vending machines sales                                  |
|                                                                  |                                                                              |                                       | No self-service sales, except in adult-only establishments |

### III. OVERSIGHT AND ENFORCEMENT

**FDA Authority.** Given the addictive, disease-causing nature of tobacco products, full and appropriate regulation is needed. Therefore, in addition to establishing new advertising and marketing restrictions, the KIDS Act would assure that FDA has the authority to effectively monitor and regulate the manufacture and distribution of tobacco products, promote the development of safer alternatives, and to conduct research. For these purposes, the KIDS Act would allocate \$300 million over and above those provided in the annual appropriations process. Importantly, FDA would not be required to overcome

provided in the annual appropriations process. Importantly, FDA would not be required to overcome special burdens or procedural hurdles in its regulatory activities — a major flaw of the June 1997 Tobacco Agreement. The KIDS Act would classify “nicotine” as a drug, and “tobacco products” as drug delivery devices (to include cigars, pipes and loose tobacco). In addition, our legislation would authorize FDA to implement a “public health” standard in its review of tobacco products.

The FDA’s authority over tobacco products would be no more and no less than its authority over other drugs and devices. However, because of the addictive nature of tobacco products, and the high prevalence of their use, the KIDS Act would specifically prohibit the FDA from banning the sale of tobacco products to adults. Finally, the KIDS Act would ensure that FDA has appropriate access to tobacco industry documents to carry out its responsibilities.

***Ingredient Disclosure.*** Evidence strongly suggests that tobacco companies design and manufacture their products to satisfy and enhance nicotine dependence. Therefore, increased information about the role and function of tobacco additives is essential to the effective regulation of such products. The KIDS Act would substantially strengthen current ingredient disclosure requirements for tobacco manufacturers. For example, each company would be required, by brand and content, to submit lists of all tobacco additives. Further, if the Secretary of Health and Human Services determines that any of these additives pose a particular risk to smokers or others exposed to tobacco smoke, this information will be fully and promptly disclosed to the public.

***Reduced Risk.*** Much remains unknown about the feasibility and effectiveness of developing a less hazardous tobacco product. However, it is clear that tobacco manufacturers have the ability and knowledge to modify their products. Indeed, various forms of “reduced risk” nicotine delivery devices already have been introduced into the market. The KIDS Act would provide increased monitoring of new technologies and facilitate broad market availability of all innovations which effectively reduce the risk of tobacco use.

***Licensing.*** There are approximately one million tobacco outlets in the United States, and as recently as 1994, nearly three quarters sold tobacco products to minors. These include supermarkets, newsstands, hotels, gas stations, convenience stores, and other types of vendors. In light of the number and variety of such outlets, a tobacco retailer licensing program is critical to ending the illegal sale of tobacco products to minors. The KIDS Act would establish a state licensing program for retailers and distributors of tobacco products similar to the system now in place for alcoholic beverages. Additionally, tobacco manufacturers would be required to obtain federal licenses. These licenses could be revoked for noncompliance with state or federal law.

## **IV. STOPPING CHILDREN FROM SMOKING BEFORE THEY START**

***Prevention in Communities and Schools.*** In addition to economic incentives, changes in tobacco product advertising and marketing, and improved oversight and enforcement, experts agree that a comprehensive slate of public health activities is needed to stop children from taking up this deadly habit. For example, research-tested school programs have proven to consistently and significantly reduce adolescent smoking. Therefore, the KIDS Act would provide \$1.4 billion to states for community and school-based prevention activities. These initiatives would be designed and implemented at the local level to ensure their effectiveness.

Because minority and low-income populations suffer a disproportionate burden of tobacco-related disease, and are among the greatest users of tobacco products, the KIDS Act would allocate a portion of the funding for community-based prevention activities to address their special needs. Funding also would be provided to assist Native American populations in their efforts to prevent and reduce youth smoking.

smoking.

**Counter Advertising.** Research findings show that well-designed counter advertising initiatives do help to reduce teen smoking. Thus, an intensive, sustained media campaign at the state and federal level is needed to “deglamorize” tobacco use among young people. Accordingly, the KIDS Act would provide \$750 million annually to fund a nationwide campaign with national, state, and local components. Preeminent advertising firms with proven expertise in the formulation of messages aimed at children would be charged with the development and implementation of “deglamorization” campaigns.

## V. HELPING CURRENT SMOKERS KICK THE HABIT

**Smoking Cessation.** While the primary emphasis of our proposal is to reduce tobacco use among children, the more than 48 million adult Americans who currently smoke deserve and need help in kicking the habit. The KIDS Act would establish a coordinated federal and state-based initiative to increase access to, and awareness of, effective programs. When fully implemented, the legislation would provide \$1.5 billion annually for programs designed to enhance existing employer-based initiatives, and those which target uninsured and under-served populations.

## VI. EXPANDING RESEARCH

**National Fund for Health Research.** Tobacco products kill more than 400,000 Americans every year — more deaths than from AIDS, alcohol and drug abuse, car accidents, murders, suicides, and fires combined. To stop this epidemic, we must strengthen our national commitment to finding preventive measures and cures for diseases — especially those related to tobacco use, including cancer, heart disease, emphysema and stroke. Therefore, the KIDS Act would establish a National Fund for Health Research to allocate resources over and above those provided to the National Institutes of Health (NIH) in the annual appropriations process. The KIDS Act would allot \$3.225 billion per year to the Fund.

**Prevention and Cessation Research.** While we know a great deal about reducing tobacco use, much remains unknown. Therefore, a significant expansion of prevention and cessation research is critical to the success of any comprehensive effort to reduce tobacco use. In particular, more information is needed on why people use tobacco and on what program interventions are most effective. Efforts must also be undertaken to increase our understanding of the health effects of tobacco use and exposure to second-hand smoke. The KIDS Act would provide \$625 million per year for a major new research effort.

## VII. HELPING THE VICTIMS OF TOBACCO-RELATED DISEASES

The KIDS Act would fully preserve the rights of individuals and groups to utilize the civil justice system to recover tobacco-related damages. Unlike the June 1997 Tobacco Agreement and some of the legislation currently pending in Congress, **the KIDS Act would not ban class action lawsuits or punitive damage awards, as the tobacco industry has sought.**

**Simply put, it would provide no immunity to the tobacco industry. Given the industry’s behavior, such liability protections cannot be justified or condoned. Furthermore, our legislation would provide no protections from, or limitations on criminal prosecution of the tobacco industry.**

**National Victims’ Compensation Fund.** To ensure that resources are readily available for the victims of tobacco-related diseases, the KIDS Act would provide for the establishment of a pre-funded National Victims’ Compensation Fund (the “Fund”), from which court awards and settlements would be paid. Furthermore, given the uncertainty of the legal environment surrounding tobacco litigation, an additional

Contingency Reserve Account would be established within the Fund. The Fund and the annual cap would be indexed to medical inflation.

- **Annual Base Payment:** At the beginning of each year, the tobacco industry would make a Base Payment of \$4 billion into the Fund; awards and settlements would be paid from this base amount. At the end of every year, any unobligated funds from the Base Payment would be deposited into an interest-bearing Contingency Reserve Account.

- **Out-of-Pocket Supplement and Annual Cap:** If awards and settlements exceed the Base Payment during any year, the industry would be liable for an additional \$4 billion in out-of-pocket payments to cover the excess, for a total potential annual liability payment by the tobacco industry of \$8 billion. This cap would not include payments made to states in settlement of existing Attorneys General suits, and would apply only to civil claims against past wrongdoing by the industry.

- **Contingency Reserve Account:** As a further protection for claimants, the KIDS Act would establish a Contingency Reserve Account (the "Account") within the Victims' Compensation Fund. Any unobligated funds from the \$4 billion Base Payment would be placed in the Account. For example, if awards and settlements paid in the first year amounted to \$1 billion, the remaining \$3 billion would be deposited into the Account. Funds in the Account would build up substantially in the early years as settlements and awards during this period are expected to be relatively small. For any year in which liability awards and settlements exceed \$8 billion, the Account would be drawn down to make the excess payments. In the unlikely event that awards and settlements ever deplete the Account in any year, unpaid claims would be rolled over and paid from the Base Payment at the beginning of the following year.

If the Account accumulates a balance of \$20 billion, the Attorney General, in conjunction with the Secretary of Health and Human Services, would determine whether to continue to deposit excess funds therein, or to redirect those funds to anti-smoking and other public health activities authorized under the legislation.

- **Small Claimant Protection:** Under the KIDS Act, individuals and smaller classes of individuals would be given priority in disbursements from the Fund to ensure that large awards or settlements, paid to 3rd parties for example, would not deny smaller claimants timely payment of their claims.

- **Settlement of State Suits and Castano Class Action:** Forty state Attorneys General have brought suits against the tobacco industry to recover costs incurred for tobacco-related illnesses and other damages. The KIDS Act would provide states the opportunity to settle their suits in exchange for funding from the National Tobacco Trust Fund established under this Act. In addition, the Castano Class Action lawsuits would be settled in return for the establishment of smoking cessation programs.

## VIII. ENDING TOBACCO INDUSTRY SECRECY

For decades, to the severe detriment of the public health, the tobacco industry has concealed evidence of the consequences of tobacco use and deliberately misled the public. Moreover, tobacco manufacturers have broadly misused the doctrine of attorney-client privilege to cloak industry documents and research in a veil of secrecy. The KIDS Act would require tobacco companies and their agents — as a precondition of eligibility for the annual cap on awards and settlements — to waive attorney-client privilege for key documents relating to the health effects, safety, and marketing of their products to children. This reform would assist the victims of tobacco-related diseases in securing judgments against tobacco companies, and out-of-court settlements, without the traditional barriers and costs associated

with document discovery.

As a further step to assure full disclosure of appropriate documents, the annual liability cap would not apply to any awards or settlements stemming from a case in which it is found that documents were not disclosed, as required under this Act, by the industry or a specific manufacturer.

***FDA to Obtain Needed Documents.*** Tobacco companies would be required to turn over to the FDA all documents the agency deemed necessary to carry out its regulatory responsibilities — including assessing the health effects of nicotine and other tobacco ingredients, the design and development of “less hazardous” or “safer” tobacco products, as well as the advertising, marketing and promotion of such products.

***Document Depository.*** The establishment and administration of a document depository would be competitively awarded to a nongovernmental entity with no connections to the tobacco industry. Tobacco manufacturers and their agents would be required to submit all documents discovered through any litigation to this depository, along with an index in such form that would make the documents easily accessible and usable by plaintiffs and researchers.

## **IX. TRANSITION ASSISTANCE TO FARMERS**

Changes in national policy regarding tobacco products, and the expected decline in their consumption, will have ramifications for farming families, workers and communities in tobacco growing regions. The KIDS Act would provide \$15 billion for compensation, income support and transitional assistance to tobacco farming families, and for economic development and related assistance in tobacco-dependent communities.

## **X. ASSURING CLEAN INDOOR AIR**

Our knowledge is growing daily on the deleterious effects of exposure to Environmental Tobacco Smoke (ETS) in the home, the workplace and other public facilities. Annually, 3,000 Americans die of lung cancer caused by second-hand smoke, and 15,000 children under 18 months of age are hospitalized with respiratory infections related to ETS exposure.

Thus, the KIDS Act would provide strong protections for workers and the public against exposures to ETS. In addition, our bill would place significant emphasis on reducing ETS exposure in the home -- including such measures as pediatric outreach, public service announcements, and comprehensive media campaigns.

The KIDS Act would also require Congress to comply with the “no smoking” policies already in place throughout the Executive Branch. Furthermore, legislation would not preempt states and local governments from establishing even more stringent policies to protect individuals from ETS.

## **XI. STOPPING SMUGGLING AND SHOWING WORLD LEADERSHIP**

In some countries, significant increases in cigarette prices have resulted in large-scale smuggling operations. Contraband cigarette trafficking can occur both at national borders and between states with wide disparities in tobacco excise taxes. Since 1992, this criminal activity has increased by more than 500% in the United States. As the price of cigarettes increases as a result of tobacco settlement legislation, actions must be taken to prevent the wide availability of contraband cigarettes.

***Tough Anti-Smuggling Initiative.*** In addition to licensing all tobacco product sellers in the stream of commerce, the KIDS Act would allocate \$300 million per year to implement an aggressive, well-coordinated anti-smuggling program aimed at stopping contraband tobacco products from entering or being sold in the United States. The bill would facilitate substantial coordination of international, federal and state law enforcement activities, as well as providing new resources to expedite the deployment of innovative anti-smuggling technologies.

***Harsh New Penalties to Stop Smuggling.*** To further deter contraband trafficking in tobacco products, the KIDS Act would also establish harsh new criminal and monetary penalties for individuals convicted of such offenses.

***World Leadership.*** The World Health Organization (WHO) currently estimates that tobacco use causes three million deaths per year worldwide — a number which is expected to increase exponentially as the U.S.-based tobacco industry intensifies its global marketing and promotional activities. By the year 2023, WHO projects tobacco-related mortalities will jump to ten million, with nearly 70 percent occurring in developing countries. This troubling trend is expected to accelerate with the enactment of strong anti-tobacco policies in the United States.

Unlike the June 1997 Tobacco Agreement, our bill would provide clear leadership on international efforts to curb tobacco use. The KIDS Act would terminate all support for tobacco promotion overseas by the United States Government, provide \$100 million per year to fund global education efforts, and encourage America's participation with other nations in efforts to harmonize tobacco policies worldwide.

## **XII. INDUSTRY CONSENT DECREES**

Voluntary, but legally-binding consent decrees — signed by federal and state governments and tobacco manufacturers — are critical to the success of any comprehensive tobacco legislation aimed at significantly reducing tobacco use by children. Without these decrees, key provisions of such a law could be delayed by lengthy legal challenges. To help avoid this problem, the KIDS Act would require tobacco companies to sign legally-binding consent decrees in order to receive the benefits of the annual liability cap established under the legislation. Violation of any of the terms of the consent decrees would result in exclusion of that company from the annual liability cap. Among other things, the consent decrees — which would be enforceable by the U.S. Attorney General or State Attorneys General through federal and state courts — would commit the companies to abide by the following agreements:

- Not to directly or indirectly bring or support legal challenges to the implementation of any aspect of the KIDS Act, including existing or future FDA regulatory authority, document disclosure, youth look-back survey methodology and penalties, and advertising and marketing restrictions;

- To pay and fully pass through the cost of annual industry payments and industry-wide look-back penalties, assuring that the price of cigarettes would increase by at least \$1.50 per pack over 2 years, with comparable increases for other tobacco products;

- All reforms related to the labeling, sale, advertising and promotion of tobacco products intended by this Act;

- Not to directly, or through contractors, lobby federal, state or local governments against any provision of this Act;

- To only do business with those retailers and distributors in full compliance with all provisions of this Act;
- To dissolve the Tobacco Institute and other existing trade associations;
- Not to advertise over the Internet; and,
- To comply also with all of the marketing and advertising restrictions in both the FDA regulation and the proposed June 1997 Tobacco Agreement.

### **XIII. ANNUAL TOBACCO PAYMENTS AND SPENDING**

**Industry Payments:** The KIDS Act would require a non-deductible industry payment of \$10 billion immediately upon enactment. That payment would be used by states and local communities, as well as the federal government, to begin implementation of the strong anti-tobacco measures authorized under the Act.

One year after enactment, the tobacco industry would make a payment of \$20 billion to the National Tobacco Trust Fund. Each year thereafter, the industry payment would be \$25 billion, indexed to inflation.

**Payments to States:** As under the June 1997 Tobacco Agreement, \$193.5 billion over 25 years would be reserved for state use. Of those funds, 50% would be distributed to states to use for improving early education, child care, or other purposes at their discretion. The remaining 50% would be allocated to the states for the purposes of tobacco prevention, education, and cessation, and for the expansion of existing public health or children's health programs.

Additionally, \$500 million per year would be awarded from the Performance Bonus Pool to states which meet or exceed their Annual Youth Reduction Targets.

**Payments for National Efforts:** Under the KIDS Act, \$4 billion of the industry's yearly payment would be directed to the National Victims' Compensation Fund as the Annual Base Payment. Remaining industry payments would be used exclusively for national anti-tobacco and public health purposes.



*Tobacco Harkin*

THE VICE PRESIDENT  
WASHINGTON

March 12, 1998

The Honorable Tom Harkin  
The Honorable John Chafee  
The Honorable Bob Graham  
U.S. Senate  
Washington, D.C. 20510

Dear Senators Harkin, Chafee and Graham:

Congratulations on your introduction of the first bipartisan comprehensive bill to drastically reduce youth smoking which encompasses the President's five principles. I regret that I cannot be there with you today as we take another crucial step forward in the fight to protect young people from the addiction and disease of tobacco and the next big step toward writing tough anti-tobacco measures into law.

We all know that ultimately any successful bill must have broad bipartisan support. I have been pleased to see that support for tough anti-tobacco measures crosses all lines of party and politics. Now, we must seize this historic opportunity, and build on this growing coalition.

The President and I look forward to working with you and others in the Congress to enact tough anti-tobacco legislation this year. We would like to work with you to ensure that any legislation sent to the President encompasses the five principles he has outlined: (1) a price increase of up to \$1.50 per pack and tough penalties if youth smoking reduction targets are not met; (2) reaffirmation of the FDA's authority to regulate tobacco products; (3) changes to the way the industry does business so it will no longer market its products to children; (4) progress toward other public health goals; and (5) protection of tobacco farmers and their communities. Further, we look forward to working with you to ensure that the revenues raised through any tobacco legislation will be invested in programs, which the President has outlined, to benefit our children.

The President and I want this Congress to be remembered as the Congress that finally protects our children from nicotine addiction and disease - and gives America the healthy kids and families we deserve.

Sincerely,

Al Gore

AG/td

March 12, 1998

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REMARKS BY THE PRESIDENT TO THE NATIONAL ASSOCIATION OF  
ATTORNEYS GENERAL

11:16 A.M. EST

THE WHITE HOUSE

Office of the Press Secretary

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For Immediate Release

March 12, 1998

REMARKS BY THE PRESIDENT  
TO THE NATIONAL ASSOCIATION OF  
ATTORNEYS GENERAL

The Washington Court Hotel  
Washington, D.C.

11:16 A.M. EST

THE PRESIDENT: Thank you very much. Attorney General Doyle. Attorney General Reno, thank you for joining us here today and for the work you have done with the states' attorneys general and local prosecutors on domestic violence and to reduce the crime rate and a whole host of other issues. I want to thank Fred Duval for the work he does on my behalf with you and this association. And I'd also like to thank the two former attorneys general that are working for me -- Bonnie Campbell, who heads the Attorney General's effort on violence against women; and Chuck Burson, who was formerly president of NAAG, now the Vice President Counsel.

I've really been looking forward to coming over here today. I have had the opportunity to know and work with most of you personally, and I see some former attorneys general out in the

audience who were my colleagues and friends. I thank them for being here.

It used to be a staple of all my speeches that the best job I ever had was being an attorney general, and to me it was. I didn't have to hire or fire anybody -- (laughter) -- except the people on the staff. I didn't have to appoint or disappoint anybody. (Laughter.) Every unpopular thing I did I blamed on the Constitution. (Laughter.) Now I'm just a punching bag from time to time -- (laughter) -- who's grateful to have an Attorney General. It's a very interesting thing. (Laughter and applause.)

On a more serious note, I loved the job that you now hold. And I suspect that I ran for it for the same reason you did -- I wanted to protect families and consumers and enforce the law. And you have been very strong allies of our administration and good partners in those endeavors, and I thank you for that very much. In many ways, we are still colleagues -- whether it's on domestic violence or reducing crime or giving our young people a more positive future.

Now we're working together to bring our country to the verge of one of the greatest public health achievements in the history of our nation -- a historic triumph in our fight to protect our children from the deadly threat of tobacco. Together we have waged a great struggle in the courts, in the Congress, across the negotiation tables and in our communities, where our children have been the targets of mass-marketing schemes and where you have been on the front lines to protect them from this effort to get them involved in addiction to tobacco.

We've made a lot of great strides in just a few years. And whenever I talk to any of you who are involved in this, naturally enough, we're always talking about what the present state of play is and what all the various issues are and what's going to happen tomorrow or what happened yesterday. And we can talk about that some

more, too. But what I'd like to do is take just a few moments to see how far we've come and then to visualize the outcome that I believe we will achieve -- first, to look back and see why we ever took on the tobacco companies in the first place when, when some of you filed your suits it was laughable -- people said it was a fight that was unwinnable; and, second, to look ahead to the end of the day -- what

we have to do to win the fight, to ensure a healthier, stronger America for our children in the new century.

We are poised to enter this new century stronger than we have been in decades. This is a great moment for our country, full of opportunity. We have the lowest unemployment rate in 24 years, the lowest inflation rate in 30 years, the highest home ownership in history, smallest welfare rolls in 27 years, the lowest crime rate in 24 years. It is a great moment of opportunity.

We have a chance to open vistas of peace and prosperity and freedom that our people have never before known. Because most of the next century will belong to our children and grandchildren instead of to ourselves, we, all of us together, have worked these last five years to give them a future of safety, health and security. We've done a lot of specific things in addition to the economic and crime and welfare statistics that I talked about. Here in Washington we have worked with many of you to implement a zero tolerance policy to keep guns and drugs out of schools. The v-chip and the television ratings and educational television have helped parents to strengthen the values as well as the minds of our children.

We've worked to bring order and discipline to our children's lives by supporting community reform efforts like curfews, school uniforms, tougher truancy laws; and to bring hope into their lives by supporting higher educational standards and keeping schools open after hours, because, as all of you know, most juvenile crime is committed when the school doors close for the day, but before the parents get home from work. We've worked to support community service, from America Reads to AmeriCorps to America's Challenge. And now we're helping to get millions of uninsured children the health insurance they need.

This is a moment of great opportunity, but also of great obligation. And we have to build on this powerful momentum to make the future we want for our children. To me, that's the most important thing that you are doing in the tobacco litigation.

It is so easy in good times to relax, but you and I both know that the world is changing so rapidly that whatever is happening today, there will be something different happening tomorrow. The sheer volume of knowledge is doubling every five years now. We are literally, because of human genome research we are literally solving problems in a matter of days that took years to solve not long before I took office. The worldwide web is growing by something like 65,000

web sites an hour now. When I took office, there were 50 -- (laughter) -- 50. Think about that. Just a little over five years ago the web was the province of a handful of scientists, physicists, started by a government research project in the Defense Department. The government, quite properly, having done the basic research and getting it up and going, got out of the way, and now it's the fastest growing organ of human interaction ever, in all of human history.

I say that again to hammer home the fact that when people have confidence because times are good, but leaders know times are changing, there is a heavier than normal responsibility to do the hard things for tomorrow. That is why it is so important that you have engaged this tobacco issue. I cannot overstate it. You know quite well that smoking kills more people every day than AIDS, alcohol, auto accidents, murders, suicides, drugs and fires combined; and that nearly 90 percent of smokers lit their first cigarette before they turned 18. David Kessler, the former FDA Commissioner, called smoking a pediatric disease. Today and every day, 3,000 children start smoking illegally; and 1,000 will have their lives shortened as a result. This is a national epidemic. It is a national tragedy. We must struggle to end it until we prevail.

Just last month, the Journal of the American Medical Association concluded that advertisements and promotions were even more crucial than peer pressure in getting teens to start smoking. Now, the law says that they can't advertise tobacco products on television or radio, but you can't escape the ads anywhere else -- in our magazines, our sports centers, on billboards. Tobacco is one of the most heavily advertised products in America.

In the early 1990s, Joe Camel alone had an advertising budget of \$75 million. He could have run for President. (Laughter.) And that's a pretty good investment from the tobacco companies' point of view. More 3- to 6-year-olds can recognize Joe Camel than Mickey Mouse.

The advertisements have taken a deadly toll. That's why you began to bring your lawsuits. That's why in 1995 I launched a nationwide effort to prevent our tobacco companies from advertising to children, to educate children about the dangers of smoking, to reduce children's access to tobacco products. Working with the FDA, we made it the law of the land essentially what was already the law in your states -- no sale of products to anyone under 18, required ID showings for anyone under 27 to make sure teens don't buy cigarettes. And I'm very proud that last year the courts upheld this authority.

Without the foresight and courage and determination of the attorneys general the progress would not have occurred. You put tobacco companies on the stand in courtrooms across America. You brought them to the bargaining table; you extracted important concessions. You raised awareness of tobacco's tragic cost to our economy and our children. You got documents out that needed to be out. Your work has been essential and the American people owe you an eternal debt of gratitude.

The worst part of this epidemic is that it isn't the product of deadly natural forces raging out of control, but a sophisticated, deliberate marketing campaign targeted at our children. I don't know how many of you saw it over the weekend, but there was a story that I saw on at least two different networks about this deadly virus that gets into small rats in the Southwest, and because of El Nino and the warming, the area of influence of this little animal is larger. And the couple of hundred people that have gotten this infection from the mice, the small mice, in the last four years -- the fatality rate has been 50 percent.

We spend a lot of time in our administration trying to make sure that the National Institutes of Health and the CDC has the investment they need both to do the research and then to set up the mechanisms to deal with the spread of disease. And as more and more of us travel to faraway places, and more and more people from faraway places travel to us, and we meet strangers in the airport, one of the great challenges of the 21st century will be the spread of disease. One of the things that global warming has done is to raise mosquitoes bearing malaria to higher and higher altitudes now, so more and more people are exposed to it. Then they travel and more and more people come in contact with it. There is now an actual public health phenomenon called airport malaria.

I'm saying that not to scare you -- we'll figure out how to handle it, we'll deal with it -- (laughter) -- but the point is that this is what we ought to be worried about. That is we ought to be worried about those things that are arising out of the natural course of events over which we have no control, that require a public health response. We should not have to worry about things that are the deliberate result of calculated decisions to make money. We shouldn't do that. (Applause.)

If it hadn't been for your efforts we might have had to wait another 30 years for the documents that have confirmed our worst

suspensions. You did that. For years we've known cigarette makers study kids' habits and tastes, preying on them with targeted marketing. Joe Camel t-shirts, Virginia Slims rock concerts, toy race cars emblazoned with tobacco company logos -- the free giveaways tell the tale.

Just last year some tobacco companies wanted to market what some called a kiddie-pack -- smaller, more affordable packs of cigarettes, sort of a starter kit. And I was in a community last week in which a person concerned about this told me that more and more cigarettes were being sold to children one by one, for a quarter apiece.

Now, as the documents are released, we begin to learn the whole story. In an internal document, one company proudly described its brand as, "the brand of choice among teenagers." Another described its plan to flavor cigarettes with apples, honey or Coca-cola because, "it's a well-known fact that teenagers like sweet products." Another company memorandum put it even more bluntly -- the 14 to 24 age group, it says, "represent tomorrow's cigarette business." And tomorrow's Medicare and Medicaid bills and hospital wards and premature funerals.

This avalanche of evidence is bringing down the walls of deceit. Now we know the facts. Now you have acted. Now Congress must act. Congress must pass comprehensive tobacco legislation that gets the industry out of the business of marketing cigarettes to our children. Thirty years of deception -- now Congress must act to bring it to an end. Thirty years of manipulation -- Congress must now act to bring it to an end. And it must act now. (Applause.)

Most Americans have 200 days left in their work calendar this year. But the work calendar schedule in Washington is only 68 days -- partly because it's an election year, partly because of things that are scheduled for holidays, partly because members do have to go home, legitimately, and work in their home states and districts. I say that to say 68 days is not a lot left this year, but it's more than enough to get this job done. The attorneys general have proved that this is not an issue of party, but an issue of principle. It's not an issue that divides America, but one that can unite us.

I was in Utah the other day -- not exactly the strongest Democratic state in America. (Laughter.) And I was with Senator Bennett and Governor Leavitt and the two House members, and I said,

it's wonderful that I'm here in Utah with my family just as this tobacco fight is opening; it's the only issue I can think of that all of Utah is to the left of me on. (Laughter.) And praise the Lord for the Mormon Church. (Laughter.)

But it's a funny story, but it illustrates a very serious and sober point. This is an American issue. This is not about politics. Believe me, there is a solid majority of Congress in both Houses, comprised of members of both parties, who want to do this and do this right. Now, it's a complicated issue -- there are complicated questions of the jurisdiction in the Congress, which committees and subcommittees should have this piece or that piece of the legislation. A lot of people are having trouble with how you work out the future liability of the tobacco companies, and how much to give up in return for the advertising fix that we want, which otherwise may not prevail in the courts. You know, there are all these questions out there.

But what I want to tell you is that we can do this. And you have to help us do this. You have to go to the Congress and say, a thousand kids a day is too high a price to pay for another year's delay. (Applause.) Thank you. Thank you very much. I think we should say clearly and simply that Congress should not go home until it passes comprehensive tobacco legislation. This is one thing that has to be done this year. (Applause.)

Now, I have said I would support any comprehensive bipartisan legislation if it meets five principles: I believe it must raise the price of cigarettes by up to \$1.50 a pack over the next decade and impose tough penalties on companies that continue to sell to kids. It must reaffirm the FDA's authority to regulate tobacco products. It must get the tobacco companies out of the business of marketing to our children. It must further our other public health goals and it must protect the tobacco farmers and their communities. And I take it we're all agreed on that; I think that is very important.

Today, I'm happy to report that Senators John Chafee, Bob Graham and Tom Harkin are introducing the first bipartisan bill that meets all five of these principles, and I strongly support their effort. It is a good, tough bill. I hope it gets wide support. The evidence is clearer than ever that this legislation will save lives. We have now a recent study that says if Congress acts, we can cut teen smoking by almost half in the next five years alone. That means

we can stop almost 3 million children from beginning. That means we can prevent almost 1 million premature deaths.

Again, I say, sure, there will be important issues to be worked out, even among allies. Even among yourselves, you have to worry about that. I know that. But if you decide that you have to act, then you figure out a way to work out the issues. This 30-year struggle also, I will say, is not about money. There are some budget and spending issues in Congress between me and the Democrats and the Republicans -- three or four or five different ideas. But if we just remember this is not about money, it's not about the size of the prize we can extract from the tobacco industry, it is about fulfilling our responsibilities to our children -- as parents, as a government, as a nation.

You have shown enormous courage and foresight in helping us get where we are today. Again, I would say, in the heat of the moment do not forget how far we have come. If someone had told me just a couple of years ago we would be here today, hardly a one of you would have believed it. Be proud of what you have done, but bring all your influence to bear on the Congress. It's not a question of party, it's a matter of principle. And it will have a very great deal to do with what your country looks like when your children are sitting where you are today.

Thank you very much, and God bless you. (Applause.)

END

11:40 A.M. EST

# **Final Report**

## **of**

# **The Advisory Committee on Tobacco Policy and Public Health**

**\*\*\***

**Co-chairs:**

**C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.**

**\*\*\***

**JULY 1997**

*July 22nd*  
*HHS*

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# **Final Report**

## **of**

# **The Advisory Committee on**

Harkin/Graham/Chafee

1/29/98

Tobacco  
Harkin EW

① 1.5 - 3 yrs.

② Kennedy over FDA

③ Liability - capped liability  
\$8 b. a yr.

→ \$4 Settlement

→ allow class actions, all parties

④ Spending undecided

- mostly should go to  
tobacco-related areas

*T. Dynco*  
*Flaherty*  
REVIEW - DO NOT CIRCULATE

02/06/98 1:44 PM

-----  
105th Congress  
2d Session

cc: CR  
TF  
EK  
+return

Mr./Ms. \_\_\_\_\_ introduced the following bill; which was read twice  
and referred to the Committee on

**A BILL**

To

---

1 *Be it enacted by the Senate and House of Representatives of the United*  
2 *States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE. -- This Act may be cited as the "Tobacco Products  
5 Control Act of 1998".

6 (b) TABLE OF CONTENTS. — The table of contents for this Act is as  
7 follows:

- Sec. 1 -- Short title; table of contents.
- Sec. 2 -- Findings.
- Sec. 3 -- Purpose.
- Sec. 4 -- Scope and effect.
- Sec. 5 -- Non-preemption of more restrictive laws.
- Sec. 6 -- Definitions.

*MS*  
*U was*  
*sent copy*  
*of this*  
*to*

## TITLE I — REGULATION OF THE TOBACCO INDUSTRY

### SUBTITLE A — Jurisdiction of the Food and Drug Administration

Sec. 101 — Conforming amendments to confirm jurisdiction.

### SUBTITLE B — Device Classification; Performance Standards

Sec. 111 — Device classification.

Sec. 112 — Performance standards.

### SUBTITLE C — Regulation of Tobacco Products

Sec. 121 — Application of Federal Food, Drug, and Cosmetic Act to tobacco products.

#### "Subchapter D -- Tobacco Product Development and Manufacturing

"Sec. 545. Tobacco product access restrictions.

"Sec. 546. Tobacco product labeling and advertising.

"Sec. 547. Point-of-sale restrictions.

"Sec. 548. Required licensing of tobacco product retailers.

"Sec. 549. Minimum standards and penalties for licensing program.

"Sec. 550. Prohibition on sales to unlicensed entities.

"Sec. 551. General responsibilities of manufacturers, distributors and retailers.

"Sec. 552. Testing and disclosure of non-tobacco ingredients.

"Sec. 553. Reduced risk products.

"Sec. 554. Access to company information.

"Sec. 555. Oversight of tobacco product manufacturing.

"Sec. 556. Authority of the Secretary.

"Sec. 557. Cigarette tar yields."

### SUBTITLE D — Penalties

Sec. 131-- Penalties.

## TITLE II -- REDUCTIONS IN UNDERAGE TOBACCO USE

### SUBTITLE A — Underage Use

Sec. 201 -- Goals for reducing underage tobacco use.

Sec. 202 -- Look-back assessment.

Sec. 203. -- Definitions.

SUBTITLE B -- State Enforcement Incentives

Sec. 211 -- State enforcement incentives.

TITLE III -- TOBACCO PRODUCT WARNINGS  
AND SMOKE CONSTITUENT DISCLOSURE

SUBTITLE A -- Product Warnings, Labeling and Packaging

Sec. 301 -- Cigarette label and advertising warnings.

Sec. 302 -- Authority to revise cigarette warning label statements.

Sec. 303 -- Smokeless tobacco labels and advertising warnings.

Sec. 304 -- Authority to revise smokeless tobacco product warning label statements.

Sec. 305 -- Tar, nicotine and other smoke constituent disclosure to the public.

SUBTITLE B -- TESTING AND REPORTING OF TOBACCO PRODUCT  
SMOKE CONSTITUENTS

Sec. 311 -- Regulation requirement.

TITLE IV -- TOBACCO INDUSTRY COMPLIANCE AND EMPLOYEE  
PROTECTION FROM REPRISALS

Sec. 401 -- Corporate compliance.

Sec. 402 -- Tobacco product manufacturer employee protection.

TITLE V -- NATIONAL STANDARDS REDUCING EXPOSURE  
TO ENVIRONMENTAL TOBACCO SMOKE

Sec. 501-- Smoke-free environments.

"Title XXVIII -- The Smoke-free Environments Act

"Sec. 2801. Smoke-free environment policy.

"Sec. 2802. Citizen actions.

"Sec. 2803. Non-preemption.

"Sec. 2804. Regulations.  
"Sec. 2805. Definitions.  
"Sec. 2806. Effective date."

## TITLE VI — APPLICATION TO INDIAN TRIBES

### SUBTITLE A — APPLICATION OF ACT TO INDIAN TRIBES

Sec. 601 — Application of Act.  
Sec. 602 — Taxation.  
Sec. 603 — Tribal programs and authority.  
Sec. 604 — Licensing.

### SUBTITLE B — TOBACCO COMPENSATION AND PUBLIC HEALTH GRANTS

Sec. 611 — Settlement Fund payments.

### SUBTITLE C — OBLIGATIONS OF TOBACCO PRODUCT MANUFACTURERS

Sec. 621 — Limitations on activities.

## TITLE VII — CIVIL LIABILITY

[RESERVED]

## TITLE VIII — FUNDING

[RESERVED]

## TITLE IX — DOCUMENT DISCLOSURE

[RESERVED]

## TITLE X — MISCELLANEOUS PROVISIONS

Sec. 1001 -- Severability.

1 **SEC. 2. FINDINGS.**

2 The Congress finds that —

3 (1) The Food and Drug Administration and other public health  
4 authorities consider the use of tobacco products by the Nation's children to  
5 be a pediatric disease of epic and worsening proportions that results in new  
6 generations of tobacco-dependent children and adults.

7 (2) A consensus exists within the scientific and medical communities  
8 that tobacco products are inherently dangerous and cause cancer, heart  
9 disease and other serious adverse health effects.

10 (3) The Food and Drug Administration and other health authorities  
11 have concluded that virtually all new users of tobacco products are under  
12 legal age.

13 (4) The President, the Food and Drug Administration, the Federal  
14 Trade Commission, state attorneys general, and public health authorities  
15 recognize that tobacco advertising and marketing contribute significantly to  
16 the use of nicotine-containing tobacco products by adolescents.

17 (5) Because past efforts to restrict advertising and marketing of  
18 tobacco products have failed to curb tobacco use by adolescents, new,  
19 more comprehensive restrictions on the sale, promotion and distribution of  
20 such products are needed.

1 (6) Federal and state governments have lacked the legal and  
2 regulatory authority and resources they need to address comprehensively  
3 the public health and societal problems caused by the use of tobacco  
4 products.

5 (7) Federal and state public health officials, the public health  
6 community, and the public at large recognize that the tobacco industry  
7 should be subject to ongoing oversight.

8 (8) Under Article 1, Section 8 of the Constitution, the Congress is  
9 vested with the responsibility for regulating interstate commerce.

10 (9) The sale, distribution, marketing, advertising and use of tobacco  
11 products are activities in and substantially affecting interstate commerce.  
12 Such products are sold, marketed, advertised and distributed in interstate  
13 commerce on a nationwide basis, and have a substantial effect on the  
14 Nation's economy.

15 (10) The sale, distribution, marketing, advertising and use of such  
16 products substantially affect interstate commerce through the health care  
17 and other costs attributable to the use of tobacco products.

18 (11) Civil actions against tobacco product manufacturers and others  
19 are pending in Federal and State courts arising from the use, marketing  
20 and sale of tobacco products. Among these actions are cases brought by

1 the attorneys general of more than forty States, certain cities and counties,  
2 the Commonwealth of Puerto Rico, and other parties seeking to recover  
3 monies expended to treat tobacco-related diseases and for the protection  
4 of minors and consumers, as well as penalties and other relief for violations  
5 of antitrust, health, consumer protection and other laws.

6 (12) Civil actions have been filed throughout the United States  
7 against tobacco product manufacturers and their distributors, trade  
8 associations, law firms and consultants on behalf of individuals or classes  
9 of individuals claiming to be dependent upon and injured by tobacco  
10 products.

11 (13) These civil actions are complex, time-consuming, expensive and  
12 burdensome for both the litigants and Federal and State courts. To date,  
13 these civil actions have not resulted in sufficient redress for smokers or  
14 non-governmental third-party payers. To the extent that governmental  
15 entities have been or may in the future be compensated for tobacco-related  
16 claims they have brought, it is not now possible to identify what portions of  
17 such past or future recoveries can be attributed to their various antitrust,  
18 health, consumer protection, or other causes of action.

19 (14) It is in the public interest for Congress to adopt comprehensive  
20 public health legislation because of tobacco's unique position in the

1 Nation's history and economy; the need to prevent the sale, distribution,  
2 marketing and advertising of tobacco products to persons under legal age;  
3 and the need to educate the public, especially young people, regarding the  
4 health effects of using tobacco products.

5 (15) The public interest requires a timely, fair, equitable and  
6 consistent result that will serve the public interest by (A) providing that a  
7 portion of the costs of treatment for diseases and adverse health effects  
8 associated with the use of tobacco products is borne by the manufacturers  
9 of these products, and (B) restricting throughout the Nation the sale,  
10 distribution, marketing and advertising of tobacco products only to persons  
11 of legal age.

12 (16) Public health authorities estimate that the benefits to the Nation  
13 of enacting Federal legislation to accomplish these goals would be  
14 significant in human and economic terms.

15 (17) The Food and Drug Administration has found that reducing the  
16 use of tobacco by minors by 50 percent would prevent well over 60,000  
17 early deaths, and that the monetary value of its regulations on tobacco will  
18 save up to \$43 billion each year in reduced medical costs, improved  
19 productivity, and the avoidance of premature deaths.

1 (18) The Nation's major tobacco product manufacturers have  
2 pledged in an agreement reached with several State attorneys general that  
3 such manufacturers will comply fully with increased federal regulation and  
4 focus intense efforts on dramatic reductions in youth access and youth  
5 usage of tobacco products.

6 (19) Advertising, marketing and promotion of tobacco products have  
7 been especially directed to attract young persons, women and minorities to  
8 use tobacco products and these efforts have resulted in increased use of  
9 such products by youth, women and minorities. Past efforts to oversee  
10 these activities have not been successful in preventing such increased use.

11 (20) It is in the public interest for Congress to adopt legislation to  
12 address the public health crisis created by actions of the tobacco industry.

13 **SEC. 3. PURPOSE.**

14 It is the purpose of this Act to —

15 (1) Confirm the authority of the Food and Drug Administration to  
16 regulate tobacco products under the Food, Drug and Cosmetic Act (21  
17 U.S.C. 321 et seq.), by recognizing it as the primary Federal regulatory  
18 authority with respect to the manufacture, marketing and distribution of  
19 tobacco products.

1 (2) Require the tobacco industry to fund both Federal and State  
2 oversight of the tobacco industry from on-going payments by tobacco  
3 product manufacturers.

4 (3) Require the Food and Drug Administration to ban all outdoor  
5 tobacco advertising and to eliminate cartoon characters and human figures  
6 in tobacco advertising because such characters and figures are especially  
7 attractive to the Nation's youth. SHOULD THIS BE IN THE ACT, AND THE  
8 CONSENT DECREE, AND THE SETTLEMENT AGREEMENT??

9 (4) Require tobacco product manufacturers to provide ongoing  
10 funding to be used for an aggressive Federal, State and local enforcement  
11 program and for a nationwide retail licensing system to prevent minors  
12 from obtaining tobacco products, while expressly permitting the States to  
13 adopt additional measures that further restrict or eliminate the products'  
14 use.

15 (5) Ensure that the Food and Drug Administration and the States  
16 may continue to address issues of particular concern to public health  
17 officials, especially the use of tobacco by young people and dependence  
18 on tobacco.

1           (6) Impose severe financial surcharges on tobacco product  
2 manufacturers if they do not substantially reduce tobacco use by young  
3 people during the next decade.

4           (7) Authorize appropriate agencies of the Federal government to set  
5 national standards controlling the manufacture of tobacco products and the  
6 identity, public disclosure and amount of ingredients used in such products.

7           (8) Provide new and flexible enforcement authority to ensure that the  
8 tobacco industry makes efforts to develop and introduce less harmful  
9 tobacco products.

10          (9) Provide the Food and Drug Administration with the authority to  
11 regulate the levels of tar, nicotine, and other harmful components of  
12 tobacco products.

13          (10) In order to ensure that adults are better informed, require  
14 tobacco product manufacturers to disclose all research which has not  
15 previously been made available, as well as all research generated in the  
16 future, relating to the health and dependency effects or safety of tobacco  
17 products.

18          (11) Impose on tobacco product manufacturers the obligation to  
19 provide funding for a variety of public health initiatives.

1           (12) Establish a minimum Federal standard for stringent restrictions  
2 on smoking in public places, with funding to enforce such standard derived  
3 from payments made by tobacco product manufacturers, while also to  
4 permit State and local governments to enact additional and more stringent  
5 standards.

6           (13) Authorize and fund from payments by tobacco product  
7 manufacturers a continuing national counter-advertising and tobacco  
8 control campaign which seeks to educate consumers and discourage  
9 children and adolescents from beginning to use tobacco products, and  
10 which encourages current users of tobacco products to discontinue using  
11 such products.

12           (14) Establish a mechanism to compensate the States in settlement  
13 of their various claims against tobacco product manufacturers.

14           (15) Authorize and fund from payments by tobacco product  
15 manufacturers a nationwide program of smoking cessation administered  
16 through State governments and the private sector.

17           (16) Establish and fund from payments by tobacco product  
18 manufacturers a Tobacco Product Liability Judgments and Settlement  
19 Fund.

1 (17) Affirm the rights of individuals to access the courts, to civil trial  
2 by jury, and to damages to compensate them for harm caused by tobacco  
3 products.

4 (18) Resolve the issue of punitive damages liability of the tobacco  
5 industry for past conduct, in recognition of payments made and  
6 comprehensive efforts to be undertaken pursuant to this Act by tobacco  
7 product manufacturers.

8 (19) Continue to permit the sale of tobacco products to adults in  
9 conjunction with measures to ensure that they are not sold or accessible to  
10 underage purchasers.

11 (20) Impose regulatory controls, including civil and criminal  
12 penalties, on the tobacco industry at least equal to those imposed on other  
13 regulated industries.

14 **SEC. 4. SCOPE AND EFFECT.**

15 (a) INTENDED EFFECT. — This Act is not intended by the Congress  
16 to--

17 (1) establish a precedent with regard to any other industry, situation,  
18 circumstance, or legal action;

(2) express any position of the Congress with regard to the imposition of punitive damages in general or as applied to any specific industry, case, controversy or product other than as provided in this Act;

(3) provide any authority regarding the imposition of, or the appropriateness of imposing, punitive damages; or

(4) except as provided in this Act, affect any action pending in State or Federal court, or any agreement, consent decree or contract of any kind.

(b) TAXATION.—Notwithstanding any other provision of law, this Act and the amendments made by this Act shall not affect any authority of the Secretary of the Treasury (including any authority assigned to the Bureau of Alcohol, Tobacco and Firearms) or of State or local governments with regard to taxation for tobacco or tobacco products.

(c) FEDERAL TRADE COMMISSION AUTHORITY.—Except as expressly provided in this Act, nothing in this Act or the amendments made by this Act shall be construed to affect any authority of the Federal Trade Commission over tobacco or tobacco products.

(d) AGRICULTURAL ACTIVITIES.—The provisions of this Act which authorize the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority under existing law of the

1 Secretary of Agriculture regarding the growing, cultivation or curing of raw  
2 tobacco.

3 **SEC. 5. NON-PREEMPTION OF MORE RESTRICTIVE LAWS.**

4 (a) AGE RESTRICTIONS.-- Nothing in this Act, the Federal Food, Drug,  
5 and Cosmetic Act (21 U.S.C. 321 et seq.), as amended by this Act, or the Food  
6 and Drug Administration Modernization Act of 1997, as amended (Public Law  
7 105-115, 111 Stat. 2296), or rules promulgated under such Acts shall prevent a  
8 Federal agency (including the Armed Forces), a State or its political subdivisions,  
9 or the government of an Indian tribe from adopting and enforcing additional  
10 measures that further restrict or prohibit tobacco product sale to, use by and  
11 accessibility to persons under the legal age of purchase established by such  
12 agency, State, subdivision, or government of an Indian tribe.

13 (b) ADDITIONAL MEASURES.-- Except as otherwise expressly provided in  
14 this Act, nothing in this Act, the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 321 et seq.), as amended by this Act, the Food and Drug Modernization Act of  
16 1997, as amended (Public Law 105-115, 111 Stat. 2296), or rules promulgated  
17 under such Acts, shall limit the authority of a Federal agency (including the Armed  
18 Forces), a State or its political subdivisions, or the government of an Indian tribe  
19 to enact, adopt, promulgate and enforce any law, rule, regulation or other  
20 measure with respect to tobacco products, including laws, rules, regulations or

1 other measures relating to or prohibiting the sale, distribution, possession,  
2 exposure to, or use of tobacco products by persons of any age that are in addition  
3 to the provisions of this Act and the amendments made by this Act. No provision  
4 of this Act or amendment made by this Act shall limit or otherwise affect any  
5 State or local taxation of tobacco products. Section 521 of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 360k) and the amendments made by section  
7 412 of the Food and Drug Modernization Act of 1997 (Public Law 105-115) shall  
8 not apply to any law, rule, regulation or other measure enacted, adopted,  
9 promulgated or enforced by a State or its political subdivisions or the  
10 government of an Indian tribe with respect to tobacco products.

## 11 **SEC. 6. DEFINITIONS.**

12 As used in this Act, the term —

13 (1) "Cigarette" means any product which contains nicotine, is intended to  
14 be burned under ordinary conditions of use, and consists of —

15 (A) any roll of tobacco wrapped in paper or in any substance not  
16 containing tobacco; or

17 (B) any roll of tobacco wrapped in any substance containing  
18 tobacco which, because of its appearance, the type of tobacco used  
19 in the filler, or its packaging and labeling, is likely to be offered to, or

1 purchased by, consumers as a cigarette described in subparagraph

2 (A).

3 (2) "Cigarette tobacco" means any product that consists of loose tobacco  
4 that contains or delivers nicotine and is intended for use by consumers in a  
5 cigarette. Unless otherwise stated, the requirements for cigarettes shall also  
6 apply to cigarette tobacco.

7 (3) "Distributor" as regards a tobacco product means any person who  
8 furthers the distribution of cigarette or smokeless tobacco, whether domestic or  
9 imported, at any point from the original place of manufacture to the person who  
10 sells or distributes the product to individuals for personal consumption. Common  
11 carriers shall not be considered distributors for purposes of this Act.

12 (4) "Indian lands" means—

13 (A) all lands within the limits of any Indian reservation;

14 and

15 (B) any lands title to which is either held in trust by the  
16 United States for the benefit of any Indian tribe or individual or  
17 held by any Indian tribe or individual subject to restriction by  
18 the United States against alienation and over which an Indian  
19 tribe exercises governmental power.

1 (5) "Indian tribe" means an Indian tribe, band, or nation, or other  
2 organized group or community, including any Native village, Regional  
3 Corporation, or Village Corporation, as defined in subsection (c), (g) or (j),  
4 respectively, of section 3 of the Alaska Native Claims Settlement Act, 43  
5 U.S.C. § 1602(c), (g) or (j)), that is recognized as eligible for the special  
6 programs and services provided by the United States under Federal law to  
7 Indians because of their status as Indians.

8 (6) "Little cigar" means any roll of tobacco wrapped in leaf tobacco or any  
9 substance containing tobacco (other than any roll of tobacco which is a cigarette)  
10 and as to which one thousand units weigh not more than three pounds.

11 (7) "Manufacturer" means any person, including any repacker or relabeler,  
12 who manufactures, fabricates, assembles, processes, or labels a finished  
13 cigarette or smokeless tobacco product.

14 (8) "Nicotine" means the chemical substance named 3-(1-Methyl-2-  
15 pyrrolidinyl)pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

16 (9) "Package" means a pack, box, carton, or container of any kind in which  
17 cigarettes or smokeless tobacco are offered for sale, sold, or otherwise  
18 distributed to consumers.

19 (10) "Point-of-sale" means any location at which a consumer can purchase  
20 or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(11) "Retailer" means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where self-service displays are permitted under subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act.

(12) "Roll-your-own tobacco" means any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

(13) "Secretary" means the Secretary of Health and Human Services.

(14) "Smokeless tobacco" means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

(15) "State" means \_\_\_\_\_.

(16) "Tobacco products" means cigarettes, cigarette tobacco, smokeless tobacco, little cigars, roll-your-own tobacco, and fine cut products.

NEED DEFINITION FOR FINE CUT

**TITLE I -- REGULATION OF THE TOBACCO INDUSTRY**

**SUBTITLE A -- JURISDICTION OF THE FOOD**

**AND DRUG ADMINISTRATION**

**SEC. 101. CONFORMING AMENDMENTS TO CONFIRM JURISDICTION.**

(a) DEFINITIONS.—(1) Section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)(C)) is amended by inserting before the semicolon at the end the following: “, including the nicotine in tobacco products”.

(2) Section 201(h)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(3)) is amended by inserting before the comma the following: “, including nicotine-containing tobacco products”.

(3) Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

“(ii) The term 'cigarette' means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of —

“(1) any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

“(2) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or

1 purchased by, consumers as a cigarette described in subparagraph

2 (1).

3 "(jj) The term 'cigarette tobacco' means any product that consists of loose  
4 tobacco that contains or delivers nicotine and is intended for use by consumers in  
5 a cigarette. Unless otherwise stated, the requirements for cigarettes shall also  
6 apply to cigarette tobacco.

7 "(kk) The term 'distributor', with respect to a tobacco product, means any  
8 person who furthers the distribution of cigarette or smokeless tobacco, whether  
9 domestic or imported, at any point from the original place of manufacture to the  
10 person who sells or distributes the product to individuals for personal  
11 consumption. Common carriers shall not be considered distributors for purposes  
12 of this chapter.

13 "(ll) The term 'little cigar' means any roll of tobacco wrapped in leaf tobacco  
14 or any substance containing tobacco (other than any roll of tobacco which is a  
15 cigarette) and as to which one thousand units weigh not more than three pounds.

16 "(mm) The term 'manufacturer', with respect to a tobacco product, means  
17 any person, including any repacker or relabeler, who manufactures, fabricates,  
18 assembles, processes, or labels a finished cigarette or smokeless tobacco  
19 product.

1       "(nn) The term 'nicotine' means the chemical substance named 3-(1-  
2 Methyl-2-pyrrolidiny)pyridine or C[10]H[14]N[2], including any salt or complex of  
3 nicotine.

4       "(oo) The term 'package', with respect to a tobacco product, means a pack,  
5 box, carton, or container of any kind in which cigarettes or smokeless tobacco are  
6 offered for sale, sold, or otherwise distributed to consumers.

7       "(pp) The term 'point-of-sale' means any location at which a consumer can  
8 purchase or otherwise obtain cigarettes or smokeless tobacco for personal  
9 consumption.

10       "(qq) The term 'retailer', with respect to a tobacco product, means any  
11 person who sells cigarettes or smokeless tobacco to individuals for personal  
12 consumption, or who operates a facility where self-service displays are permitted  
13 under subchapter D of chapter V.

14       "(rr) The term 'roll-your-own tobacco' means any tobacco which, because  
15 of its appearance, type, packaging, or labeling, is suitable for use and likely to be  
16 offered to, or purchased by, consumers as tobacco for making cigarettes.

17       "(ss) The term 'smokeless tobacco' means any product that consists of cut,  
18 ground, powdered, or leaf tobacco that contains nicotine and is intended to be  
19 placed in the oral cavity.

1       "(tt) The term 'tobacco products' means cigarettes, cigarette tobacco,  
2 smokeless tobacco, little cigars, roll-your-own tobacco, and fine cut  
3 products."

4                               NEED DEFINITION FOR FINE CUT

5       (4) Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
6 353(g)) is amended by inserting "(including any tobacco product)" after "products"  
7 the first place it appears.

8       (b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and  
9 Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

10       "(x) The manufacture, labeling, distribution, advertising and sale of any  
11 adulterated or misbranded tobacco products in violation of —

12               "(1) regulations issued under this Act; and

13               "(2) the Tobacco Products Control Act of 1998, or regulations  
14 issued under such Act."

15       (c) ADULTERATED DRUGS AND DEVICES.—(1) Section 501 of the  
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by adding at  
17 the end the following:

18       "(j) If it is a tobacco product and it does not comply with the provisions of  
19 subchapter D of this chapter or the Tobacco Products Control Act of 1998."

1 (2) Section 502(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2 352(q)) is amended--

3 (A) by striking "or (2)" and inserting in lieu thereof "(2)"; and

4 (B) by adding before the period the following: ", or (3) in the  
5 case of a tobacco product, it is sold, distributed, advertised, labeled,  
6 or used in violation of this Act or the Tobacco Products Control Act of  
7 1998, or regulations prescribed under such Acts".

8 (d) RESTRICTED DEVICE.-- Section 520(e) of the Federal Food, Drug,  
9 and Cosmetic Act (21 U.S.C. 360j(e)) is amended by adding at the end the  
10 following:

11 "(3) Tobacco products are a restricted device under this paragraph."

12 (e) EFFECTIVE DATE.-- The amendments made by subsections (a)(4), (b),  
13 (c) and (d) shall remain in effect for a period of five years from the date of  
14 enactment of this Act. During such period, the Secretary may revise such  
15 amendments in extraordinary circumstances. After such period, the Secretary  
16 may revise such amendments in accordance with applicable provisions of the  
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

18 **SUBTITLE B -- DEVICE CLASSIFICATION; PERFORMANCE**

19 **STANDARDS**

**SEC. 111. DEVICE CLASSIFICATION.**

Section 513(a)(1)(B) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 360c(a)(1)(B)) is amended--

(1) by inserting "(i)" after "CLASS II, SPECIAL CONTROLS--";

(2) by adding after the last sentence the following: "Tobacco products shall be classified as Class II devices"; and

(3) by adding at the end the following:

"(ii) The sale of tobacco products to individuals over the age of 18 years that comply with performance standards established for these products under section 514 and other provisions of this Act and any regulations prescribed under this Act shall not be prohibited by the Secretary, notwithstanding sections 502(j), 516, and 518."

**SEC. 112. PERFORMANCE STANDARDS.**

Section 514(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)) is amended--

(1) by inserting "non-tobacco product" before "device" the first place it appears in paragraph (2);

(2) by redesignating subparagraphs (3) and (4) as subparagraphs (6) and (7), respectively; and

1 (3) by inserting after subparagraph (2) the following:

2 “(3) A performance standard established under this section for a tobacco  
3 product device shall---

4 “(A) include provisions to reduce the overall health risks to the  
5 public based upon the best available technology, including the  
6 reduction in risk to consumers of tobacco products and the reduction  
7 in harm which will result for individuals who continue to use tobacco  
8 products, but less often, and for individuals who cease use or do not  
9 commence use of tobacco products, taking into account all factors  
10 the Secretary considers relevant;

11 “(B) where necessary to provide a reduction in the  
12 overall health risks to the public, include--

13 “(i) provisions respecting the construction,  
14 components, constituents, ingredients, and properties of  
15 the tobacco product device, including the reduction or  
16 elimination (or both) of nicotine and the other  
17 components, ingredients, and constituents of the  
18 tobacco product, its components and its by-products,  
19 based upon the best available technology;

1           “(ii) provisions for the testing (on a sample basis  
2           or, if necessary, on an individual basis) of the tobacco  
3           product device or, if it is determined that no other more  
4           practicable means is available to the Secretary to  
5           assure the conformity of the tobacco product device to  
6           such standard, provisions for the testing (on a sample  
7           basis or, if necessary, on an individual basis) by the  
8           Secretary or by another person at the direction of the  
9           Secretary;

10           “(iii) provisions for the measurement of the  
11           performance characteristics of the tobacco product  
12           device;

13           “(iv) provisions requiring that the results of each  
14           test or of certain tests of the tobacco product device  
15           required to be made under clause (ii) demonstrate that  
16           the tobacco product device is in conformity with the  
17           portions of the standard for which the test or tests were  
18           required; and

19           “(v) a provision that the sale, advertising, and  
20           distribution of the tobacco product device be restricted

1 but only to the extent that the sale, advertising, and  
2 distribution of a tobacco product device may be  
3 restricted under this Act; and

4 “(C) where appropriate, require the use and prescribe the form  
5 and content of labeling for the use of the tobacco product device.

6 “(4) Not later than one year after the date of enactment of this  
7 subparagraph, the Secretary (acting through the Commissioner of Food and  
8 Drugs) shall establish a Scientific Advisory Committee to determine the level or  
9 range of levels at which nicotine yields do not produce drug-dependence. The  
10 Advisory Committee shall also review any other safety, dependence or health  
11 issue assigned to it by the Secretary.”.

12 **SUBTITLE C — REGULATION OF TOBACCO PRODUCTS**

13 **SEC. 121. APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT**  
14 **TO TOBACCO PRODUCTS.**

15 (a) TOBACCO PRODUCTS REGULATION.—Chapter V of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at  
17 the end the following new subchapter:

18 **"SUBCHAPTER D — TOBACCO PRODUCT DEVELOPMENT**  
19 **AND MANUFACTURING**

1 "TOBACCO PRODUCT ACCESS RESTRICTIONS

2 "Sec. 545. A tobacco product shall be deemed to be misbranded —

3 "If it is sold or distributed —

4 "(1) To any individual under the age of 18 years.

5 "(2) To any individual under the age of 27 years if the retailer has not  
6 verified by a photographic identification containing the bearer's date of birth  
7 that the individual is not under the age of 18 years.

8 "(3) In any manner other than through a direct, face-to-face exchange  
9 between the retailer and the consumer, without the assistance of any  
10 electronic or mechanical device, except that mail-order sales (other than  
11 mail-order redemption of coupons and distribution of free samples through  
12 the mail) that are subject to verification that the purchaser is not under the  
13 age of 18 years shall be permitted, and self-service displays located in  
14 facilities where the retailer ensures that no individual under the age of 18  
15 years is present, or permitted to enter, at any time shall be permitted:

16 *Provided*, That the Secretary shall, within 2 years after the date of  
17 enactment of the Tobacco Products Control Act of 1998, review and  
18 determine whether persons under the age of 18 years are obtaining  
19 tobacco products by means of the mail; and, based solely upon that review,

1 the Secretary may take further regulatory and administrative action to  
2 restrict or eliminate mail order sales of tobacco products.

3 “(4) On the counter in any retail establishment where an individual  
4 under the age of 18 years is present or permitted to enter at any time, if  
5 such tobacco product is placed where it is accessible directly to  
6 consumers, or if it is placed on the counter, where it is visible or directly  
7 accessible to consumers.

8 “(5) In any manner other than in its original unopened package, can  
9 or pouch, which for cigarettes shall be an original unopened package that  
10 contains 20 cigarettes or more, and for cigarette tobacco or smokeless  
11 tobacco shall be a can or pouch that is no smaller than the smallest  
12 package distributed by the manufacturer for individual consumer use.

13 “(6) As a free sample.

14 “(7) Using a trade or brand name of a non-tobacco product as the  
15 trade or brand name of a tobacco product, except for a tobacco product  
16 whose trade or brand name was on both a tobacco product and a non-  
17 tobacco product that were sold in the United States as of January 1, 1995.

18 “(8) If any gift or item (other than cigarettes or smokeless tobacco) is  
19 offered in consideration of its purchase, or in consideration of furnishing  
20 evidence, such as credits, proofs-of-purchase, or coupons, of its purchase.

1           “(9) At any athletic, musical, artistic, or other social or cultural event,  
2 or any entry or team in any event, that is sponsored in the brand name  
3 (alone or in conjunction with any other word), logo, symbol, motto, selling  
4 message, recognizable color or pattern of colors, or any other indicia of  
5 product identification identical or similar to, or identifiable with, those used  
6 for the tobacco product: *Provided*, That a manufacturer, distributor, or  
7 retailer may sponsor or cause to be sponsored any athletic, musical,  
8 artistic, or other social or cultural event, or team or entry, in the name of the  
9 corporation which manufactures a tobacco product, if both the corporate  
10 name and the corporation were registered and in use in the United States  
11 prior to January 1, 1995, and if the corporate name does not include any  
12 brand name (alone or in conjunction with any other words), logo, symbol,  
13 motto, selling message, recognizable color or pattern or colors, or any  
14 other indicia of product identification identical or similar to, or identifiable  
15 with, those used for any brand of cigarettes or smokeless tobacco.

16           “TOBACCO PRODUCT LABELING AND ADVERTISING

17           “Sec. 546. A tobacco product shall be deemed to be misbranded —

18           “(a) Unless its advertising and labeling (including the package):

1           “(1) contain no human image or cartoon character; SHOULD  
2           THIS BE IN THE ACT, AND THE CONSENT DECREE, AND THE  
3           SETTLEMENT AGREEMENT??

4           “(2) are not outdoor advertising, including advertising in  
5           enclosed stadia and advertising from within a retail establishment  
6           that is directed toward or visible from the outside of the  
7           establishment; SHOULD THIS BE IN THE ACT, AND THE  
8           CONSENT DECREE, AND THE SETTLEMENT AGREEMENT??

9           “(3) are accompanied by a disclaimer in the advertising that words  
10          such as ‘light’ or ‘low tar’ describing the product do not render the product  
11          less hazardous than any other tobacco product, in addition to such other  
12          requirements as the Secretary may impose;

13          “(4) at the time the advertising or labeling is first used is submitted to  
14          the Secretary so that the Secretary may conduct regular review of the  
15          advertising and labeling;

16          “(5) comply with section 547;

17          “(6) do not appear on the international computer network of  
18          both Federal and non-Federal interoperable packet switches data  
19          networks (the ‘Internet’), unless such advertising is designed to be  
20          inaccessible in or from the United States to all individuals under the

1 age of 18 years; SHOULD THIS BE IN THE ACT, AND THE  
2 CONSENT DECREE, AND THE SETTLEMENT AGREEMENT??

3 “(7) use only black text on white background, other than (i) those  
4 locations where self-service displays are permitted under paragraph (a)(3)  
5 of section 545, if the advertising is not visible from outside the  
6 establishment and is affixed to a wall or fixture in the establishment, and (ii)  
7 advertisements appearing in any publication which the manufacturer,  
8 distributor or retailer demonstrates to the Secretary is a newspaper,  
9 magazine, periodical, or other publication whose readers under the age of  
10 18 years constitute 15 percent or less of the total readership as measured  
11 by competent and reliable survey evidence, and that is read by less than 2  
12 million persons under the age of 18 years as measured by competent and  
13 reliable survey evidence;

14 “(8) for video formats, use only static black text on a white  
15 background, and any accompanying audio uses only words without music  
16 or sound effects; and

17 “(9) for audio formats, use only words without music or sound effects.

18 “(b) If a logo, symbol, motto, selling message, recognizable color or pattern  
19 of colors, or any other indicia of product identification of the tobacco product is

1 contained in a movie, program, or video game for which a direct or indirect  
2 payment has been made to ensure its placement.

3 “(c) If a direct or indirect payment has been made by any manufacturer,  
4 distributor, or retailer to any entity for the purpose of promoting the image or use  
5 of a tobacco product through print or film media that appeals to individuals under  
6 the age of 18 years or through a live performance by an entertainment artist that  
7 appeals to such individuals.

8 “(d) If a logo, symbol, motto, selling message, recognizable color or pattern  
9 of colors, or any other indicia or product identification identical to, similar to, or  
10 identifiable with the tobacco product is used for any item (other than a tobacco  
11 product) or service marketed, licensed, distributed or sold or caused to be  
12 marketed, licensed, distributed, or sold by the manufacturer or distributor of the  
13 tobacco product.

14 “(e) Unless its package label and advertising bear the product’s established  
15 name and a statement of its intended use, as follows: ‘Cigarettes-A  
16 Nicotine-Delivery Device’; ‘Cigarette Tobacco-A Nicotine Delivery Device’; or  
17 ‘Loose Leaf Chewing Tobacco’, ‘Plug Chewing Tobacco’, ‘Twist Chewing  
18 Tobacco’, ‘Moist Snuff’, or ‘Dry Snuff’, whichever is appropriate for the product,  
19 followed by the words ‘A Nicotine-Delivery Device’.

1       “(f)(1) Except as provided in subparagraph (2), if advertising or labeling for  
2 such product that is otherwise in accordance with the requirements of this section  
3 bears a tobacco product brand name (alone or in conjunction with any other word)  
4 or any other indicia of tobacco product identification and is disseminated in a  
5 medium other than newspapers, magazines, periodicals or other publications  
6 (whether periodic or limited distribution), nonpoint-of-sale promotional material  
7 (including direct mail), point-of-sale promotional material, or audio or video  
8 formats delivered at a point-of-sale.

9       “(2) Notwithstanding subparagraph (1), advertising or labeling for cigarettes  
10 or smokeless tobacco may be disseminated in a medium that is not specified in  
11 paragraph (1) if the manufacturer, distributor or retailer notifies the Secretary not  
12 later than 30 days prior to the use of such medium. The notice shall describe the  
13 medium and the extent to which the advertising or labeling may be seen by  
14 persons under the age of 18 years.

#### 15                                   “POINT-OF-SALE RESTRICTIONS

16       “Sec. 547. (a) Except as provided in paragraph (b), no manufacturer,  
17 distributor, or retailer shall engage in point-of-sale advertising of any tobacco  
18 product in any retail establishment (other than an establishment that sells only  
19 tobacco products) in which an individual under the age of 18 years of age is  
20 present, or permitted to enter, at any time.

1           “(b)(1) A tobacco product manufacturer which has less than a 25 percent  
2 market share of all tobacco products sold in the United States (as determined by  
3 the Secretary) may place not more than two separate point-of-sale  
4 advertisements in or at each location where tobacco products are offered for sale,  
5 and a tobacco product manufacturer which has a 25 percent or more market  
6 share of all tobacco products sold in the United States (as determined by the  
7 Secretary) may place not more than three separate point-of-sale advertisements  
8 in or at each such location.

9           “(2) A retailer may place one point-of-sale advertisement in or at each such  
10 location for its brand or the contracted house retailer or private label brand of its  
11 wholesaler.

12           “(3) The display area of any such point-of-sale advertisement (either  
13 individually or in the aggregate) shall not be larger than 576 square inches and  
14 shall consist of black letters on white background or another recognized  
15 typography.

16           “(4) Any such point-of-sale advertisement shall not be attached to or  
17 located within two feet of any display fixture on which candy is displayed for sale.

18           “(d) Any audio or video format permitted under regulations promulgated by  
19 the Secretary may be distributed at the time of sale of a tobacco product to  
20 individuals over the age of 18 years, but no such format may be played or shown  
21 in or at any location where tobacco products are offered for sale.

1       “(e) No manufacturer or distributor of tobacco products may enter into any  
2 arrangement with a retailer that limits the retailer’s ability to display any form of  
3 advertising or promotional material originating with another supplier and  
4 permitted by law to be displayed in a retail establishment.

5       “(f) As used in this section, the terms ‘point-of-sale advertisement’ and  
6 ‘point-of-sale advertising’ mean all printed or graphical materials bearing the  
7 brand name (alone or in conjunction with any other word), logo, symbol, motto,  
8 selling message, or any other indicia of product identification identical or similar  
9 to, or identifiable with, those used for any brand of cigarettes or smokeless  
10 tobacco, which, when used for its intended purpose, can reasonably be  
11 anticipated to be seen by customers at a location where tobacco products are  
12 offered for sale.

#### 13       “REQUIRED LICENSING OF TOBACCO PRODUCT RETAILERS

14       “Sec. 548. (a) Any manufacturer, distributor, wholesaler, importer, or  
15 retailer that sells or arranges for the sale of any tobacco product directly to  
16 consumers shall obtain a license for such sale in accordance with such terms and  
17 conditions as the Secretary shall establish under this subchapter.

18       “(b) The Secretary shall establish minimum federal standards for licensing  
19 the sale of tobacco products, which standards shall be enforced jointly by the  
20 Secretary, State and local governments in States that establish such a program  
21 pursuant to section 549, and Indian tribes. The costs of enforcing the program

1 shall be provided from payments by tobacco manufacturers under THE  
2 TOBACCO PRODUCTS CONTROL ACT OF 1998. Nothing in this subchapter  
3 shall require States not receiving funds under THE TOBACCO PRODUCTS  
4 CONTROL ACT OF 1998 to establish such a program or preclude a State, local  
5 government or Indian tribe from adopting standards that are more restrictive than  
6 the minimum standards established under this subchapter.

7 "MINIMUM STANDARDS AND PENALTIES FOR LICENSING PROGRAM

8 "Sec. 549. (a) No State, local government, or Indian tribe may receive  
9 funds under THE TOBACCO PRODUCTS CONTROL ACT OF 1998 unless the  
10 State, local government, or Indian tribe has in effect a tobacco product sales  
11 licensing program in conformity with minimum standards established by the  
12 Secretary. Such minimum standards shall —

13 "(1) require that any such entity must obtain a separate  
14 license for each place of business where tobacco products are  
15 distributed directly to consumers prior to the sale or arranging for the  
16 sale of any tobacco product directly to consumers;

17 "(2) require that any entity must comply with applicable  
18 provisions of this Act, the Tobacco Products Control Act of 1998, and  
19 such regulations as the Secretary shall prescribe under such Acts,  
20 and with any other Federal and State laws and regulations regarding  
21 tobacco products, in order to obtain and maintain a license;

1           "(3) in accordance with paragraph (b), provide for the non-  
2 assignability of such license and for the suspension or revocation of  
3 such license, or the imposition of other penalties, for violations of this  
4 Act or the Tobacco Products Control Act of 1998;

5           "(4) require that no tobacco product shall be distributed to any  
6 entity for the purpose of resale unless such entity has obtained and  
7 maintains a license that meets the minimum standards established  
8 by the Secretary under this subchapter;

9           "(5) provide for the assessment of a fee to defray the  
10 administrative costs of issuing such licenses;

11           "(6) provide for a licensing program that complies with  
12 regulations issued under this section and is subject to the penalties  
13 provided in this section to be administered by the Federal  
14 government that is applicable to military installations, Federal  
15 government installations outside the United States, duty-free stores  
16 within the United States, and territories and possessions of the  
17 United States that are not subject to the jurisdiction of any State; and

18           "(7) provide for a licensing program that complies with  
19 regulations issued under this subchapter that is applicable to the sale  
20 of tobacco products on Indian lands.

1       "(b)(1) Any individual who knowingly sells or arranges for the sale of any  
2 tobacco product without obtaining a license in accordance with this section shall  
3 be imprisoned for not more than six months or fined not more than \$1,000, or  
4 both, for each such violation.

5       "(2) Any corporation which knowingly sells or arranges for the sale of any  
6 tobacco product without obtaining a license in accordance with this section shall  
7 be fined not more than \$50,000 for each such violation. A corporation shall be  
8 deemed to have knowingly sold or arranged for the sale of any tobacco product if  
9 its employee engages in such conduct.

10       "(3) Any licensing program established by a State, local government or  
11 Indian tribe receiving funds under THE TOBACCO PRODUCTS CONTROL ACT  
12 OF 1998 shall require that, in addition to any criminal penalties which may be  
13 imposed by the State, local government or Indian tribe, any licensee who violates  
14 any provision of State law relating to the sale of tobacco products to persons  
15 under the legal age of sale in that State shall be subject to civil penalties as  
16 follows:

17               "(A) On a site-by-site basis, suspension or revocation  
18 of a license under this section, or a combination of suspension  
19 and revocation, for any violation of a State law establishing the  
20 minimum age of an individual to whom a tobacco product may  
21 be sold.

1           "(B) A civil penalty, which shall not exceed the following:

2                       "(i) For the first offense within any  
3                       two-year period, \$500 or a 3-day  
4                       suspension of a license, or both.

5                       "(ii) For the second offense within any two-  
6                       year period, \$1,000 or a 7-day suspension of a  
7                       license, or both.

8                       "(iii) For the third offense within any two-year  
9                       period, \$2,000 or a 30-day suspension of a license, or  
10                      both.

11                      "(iv) For the fourth offense within any two-year  
12                      period, \$5,000 or a 6-month suspension of a license, or  
13                      both.

14                      "(v) For the fifth offense within any two-year  
15                      period, \$10,000 or a one-year suspension of a  
16                      license, or both.

17                      "(vi) For the sixth through ninth offenses  
18                      within any two-year period, \$25,000 or a  
19                      revocation of a license with no possibility of  
20                      reinstatement for a period of three years.

"(vii) For the tenth offense within any two-year period, permanent revocation of a license.

Each State, local government and Indian tribe receiving funds under THE TOBACCO PRODUCTS CONTROL ACT OF 1998 shall have in place penalties that are at least as stringent as the penalties set forth in this subsection. Nothing in this subsection shall prevent any State, local government or Indian tribe from adopting any penalty, or civil, criminal or administrative sanction, in addition to those specified in this subsection.

"(c) As used in this section, the term 'Indian lands' means —

"(1) all lands within the limits of any Indian reservation; and

"(2) any lands title to which is either held in trust by the United States for the benefit of any Indian tribe or individual or held by any Indian tribe or individual subject to restriction by the United States against alienation and over which an Indian tribe exercises governmental power.

#### "PROHIBITION ON SALES TO UNLICENSED ENTITIES

"Sec. 550. It shall be unlawful for any person to distribute, consign, or sell (or arrange to be distributed, consigned or sold) tobacco products to any person (including manufacturers, wholesalers, importers, distributors and retailers) engaged in the sale of any tobacco product who does not possess a valid license issued to such person pursuant to this subchapter.

1 "GENERAL RESPONSIBILITIES OF MANUFACTURERS,  
2 DISTRIBUTORS AND RETAILERS

3 "Sec. 551. Each manufacturer, distributor, and retailer shall ensure  
4 that the tobacco products it manufactures, labels, advertises, packages  
5 distributes, sells, or otherwise holds for sale comply with all applicable  
6 requirements of this Act.

7 "TESTING AND DISCLOSURE OF NON-TOBACCO INGREDIENTS

8 "Sec. 552. (a) In accordance with the provisions of this section, the  
9 Secretary shall by regulation provide for a safety assessment of all tobacco  
10 product additives under the intended conditions of use by consumers of such  
11 products. Such regulations shall prescribe the conditions under which any such  
12 additive up to a specified amount may be employed for its particular use or its  
13 intended use, or may be represented as suitable.

14 "(b)(1) Each tobacco product manufacturer shall, in accordance with  
15 regulations promulgated by the Secretary, disclose annually to the Secretary the  
16 existence and amount of all ingredients, substances and compounds (other than  
17 tobacco, water or reconstituted tobacco sheet made wholly from tobacco) which  
18 are added by the manufacturer (or at the manufacturer's direction) to the tobacco,  
19 paper or filter of the tobacco product (hereinafter in this section referred to as

1 'additives'). Such listing shall identify the ingredients, substances and  
2 compounds by brand and by precise quantity in each brand of tobacco product.

3 "(2) Any information disclosed under this paragraph shall be provided on a  
4 confidential basis and shall be subject to the public disclosure provisions of this  
5 Act. The manufacturer shall identify any additive that it believes to be exempt  
6 from public disclosure.

7 "(c)(1) Within 5 years after the date of enactment of the Tobacco Products  
8 Control Act of 1998, and according to a schedule within such time period  
9 determined by the Secretary, each tobacco product manufacturer shall submit to  
10 the Secretary a safety assessment for each additive contained at that time in any  
11 tobacco product of such manufacturer. Such assessment shall set forth, based  
12 on the best available scientific evidence, whether it is reasonably certain that the  
13 additive is not harmful under the intended conditions of use, when used in a  
14 specified amount.

15 "(2) The Secretary shall review any assessment submitted under  
16 subparagraph (1) based on whether there is a reasonable certainty in the opinion  
17 of competent scientists that the ingredient (up to a specified amount) is not  
18 harmful under the intended conditions of use. Within 180 days after any  
19 submission under this paragraph, the Secretary shall disapprove the safety and  
20 prohibit the use of any such additive. If the Secretary fails to act within such 180-

1 day period, the manufacturer may continue to use the additive up to the specified  
2 amount until the Secretary disapproves the safety of such additive.

3 “(3) Any information submitted under this paragraph shall be provided on a  
4 confidential basis. The manufacturer shall identify any additive that it believes to  
5 be exempt from public disclosure. The Secretary may challenge a manufacturer's  
6 assertion that any such additive is exempt from public disclosure under rules  
7 modeled after regulations promulgated under this Act for other products.

8 “(4) Any additive used in a tobacco product after the submission of  
9 information under subparagraph (1) shall be submitted to the Secretary at the  
10 time of its first use, and the provisions of this paragraph shall apply to such  
11 additive. If an additive is used in a tobacco product in a greater amount than its  
12 prior use, the manufacturer shall submit information regarding such use to the  
13 Secretary at the time of such use, and the provisions of this paragraph shall apply  
14 to such additive.

15 “(5)(A) Except as provided in clause (B), the Secretary or any officer or  
16 employee of the Department shall not disclose any information reported or  
17 otherwise obtained under this section, if such disclosure is prohibited under any  
18 other provision of law. Any information which is not subject to disclosure shall be  
19 considered a trade secret or other matter specified in section 1905 of title 18,  
20 United States Code, and shall not be subject to disclosure under section 552 of

1 title 5, United States Code. In addition, the Secretary shall establish additional  
2 procedures to ensure the confidentiality of such information, including the  
3 designation of an agent to supervise such information through such procedures  
4 as the storage of the information under lock, the maintenance of a record of any  
5 persons accessing such information, and securing in writing a commitment from  
6 any person accessing such information that such person will treat the information  
7 as confidential.

8 “(B) Notwithstanding the provisions of clause (A), such information may be  
9 disclosed to other officers or employees of the Department and of other agencies  
10 responsible for carrying out this chapter or when relevant in any proceeding under  
11 this chapter. Nothing in this section shall authorize the withholding of any  
12 information by the Secretary, or by any officer or employee under the Secretary’s  
13 supervision, from any duly authorized committees of the Congress.

14 “(d) During the five-year period after the date of enactment of the Tobacco  
15 Products Control Act of 1998, each additive that would be exempt from disclosure  
16 under regulations modeled after regulations promulgated under this Act for other  
17 products shall be presumed not to be subject to disclosure unless the Secretary  
18 disapproves the safety of any such additive: *Provided*, That any manufacturer  
19 shall disclose all additives which it is required to disclose with respect to a

1 particular brand in order to comply with any other law or regulation of any other  
2 Federal or State agency.

3 “(e) In accordance with regulations promulgated by the Secretary, a  
4 tobacco product manufacturer shall establish and maintain procedures for the  
5 selection, testing, purchase, storage and use of any additive in a tobacco product.  
6 The manufacturer shall maintain such records, and provide the Secretary with  
7 access to any such records, as the Secretary shall require. The Secretary shall  
8 establish procedures to ensure the confidentiality of such records in accordance  
9 with this section and any other applicable provision of law.

10 “(f) The Secretary shall promulgate regulations to carry out this section  
11 within 12 months after the date of enactment of the Tobacco Products Control Act  
12 of 1998.

13 “(g)(1) The Secretary shall promulgate regulations requiring the disclosure  
14 to the public on a brand-by-brand basis, by means of a package insert, of the  
15 common or usual name of each ingredient (other than tobacco, water, or  
16 reconstituted tobacco sheet made wholly from tobacco) of a cigarette or  
17 smokeless tobacco product in descending order of predominance by weight,  
18 except that the regulations shall provide that spices, flavorings, and colorings  
19 may be designated as spices, flavorings, and colorings without naming each such  
20 spice, flavoring, or coloring: *Provided, however,* That any ingredient that is

1 required to be disclosed to the public pursuant to any other law or regulation with  
2 respect to a particular brand shall (on and after the date of actual disclosure  
3 pursuant to such other law or regulation also be required to be disclosed for  
4 purposes of this subparagraph. The Secretary may challenge a manufacturer's  
5 assertion that an ingredient would be exempt from disclosure to consumers.

6 "(2) In accordance with regulations promulgated by the Secretary under this  
7 paragraph, incidental additives, including processing aids and chemical  
8 preservatives, that are present in a cigarette or smokeless tobacco product at  
9 insignificant levels and that the Secretary determines do not have any technical or  
10 functional effect in the cigarette or smokeless tobacco product shall be exempt  
11 from disclosure under subparagraph (1).

12 "(3) Consistent with the authority set forth in sections 514(b)(5) and 904,  
13 the Secretary shall establish a Scientific Advisory Committee to advise the  
14 Secretary on matters related to the safety of ingredients in tobacco products and  
15 to the health and other effects of such products, except that the Secretary shall  
16 not be required to have promulgated any regulation in order to establish such an  
17 Advisory Committee.

## 18 "REDUCED RISK PRODUCTS

19 "Sec. 553. (a)(1) No tobacco product manufacturer, distributor, or retailer  
20 may state or imply a reduced health risk associated with a tobacco product in

1 advertising or on a product package unless the manufacturer demonstrates to the  
2 Secretary, in such form as the Secretary may require, that based on the best  
3 available scientific evidence the product significantly reduces the risk to health  
4 when compared to other tobacco products.

5 "(2) Prior to making any such statement, a manufacturer, distributor, or  
6 retailer shall submit such statement to the Secretary, who shall review such  
7 statement to ensure its accuracy and, in the case of advertising, to prevent such  
8 statement from increasing, or preventing the contraction of, the size of the overall  
9 market for tobacco products.

10 "(b) If the Secretary determines that any such statement is accurate  
11 because the tobacco product does present a reduced health risk, the Secretary  
12 may permit such statement to be made. Notwithstanding the limitations on  
13 advertising of tobacco products contained in this Act, the Secretary may permit  
14 exceptions to such limitations if the Secretary determines that such advertising is  
15 likely to reduce harm to the public from tobacco products, taking into account  
16 whether the advertising would have the effect of increasing or preventing the  
17 contraction of the size of the overall market for tobacco products, and promote  
18 the public health. Such permission shall not be construed to constitute approval  
19 by the Secretary of any health risks presented by the product. The Secretary  
20 shall promulgate rules to implement the provisions of this paragraph.

1       "(c)(1) A manufacturer which develops or acquires any technology, or  
2       which has developed or acquired any technology, that the manufacturer  
3       reasonably believes will reduce the risk from tobacco products shall notify the  
4       Secretary of the development or acquisition of the technology, in such form and  
5       within such time as the Secretary shall require.

6       "(2) A manufacturer which develops or acquires any such technology shall,  
7       upon request of the Secretary and the payment of a reasonable fee, license the  
8       use of such technology to any other entity, if such entity is also obligated to  
9       provide the notification specified in subparagraph (1). The Secretary shall  
10      establish a process for determining the reasonableness of any such fee, in any  
11      case where the manufacturer and the requesting entity are not able to agree upon  
12      a reasonable fee.

13      "(3) With respect to any such technology that is in the early stages of  
14      development (as determined by the Secretary), the Secretary shall establish  
15      protections to ensure the confidentiality of any proprietary information submitted  
16      to the Secretary under this paragraph during such development.

17      "(d)(1) In order to ensure that tobacco products which appear to have the  
18      potential to reduce risks are tested and made available in the marketplace, the  
19      Secretary may, by means of a rulemaking conducted in accordance with section  
20      553 of title 5, United States Code, require the introduction of tobacco products

1 that present reduced health risks if such products are determined to be  
2 technologically feasible.

3 "(2) If the Secretary requires the introduction of any tobacco product under  
4 subparagraph (1), the Secretary may direct a manufacturer subject to this Act  
5 which owns the technology necessary to manufacture a tobacco product with  
6 reduced health risks to elect either (A) to introduce such technology into the  
7 marketplace, or (B) to license (for a reasonable fee) such technology to a  
8 manufacturer subject to this Act which intends to introduce the technology into the  
9 marketplace within a reasonable time. If no manufacturer or licensee introduces  
10 such technology within a reasonable time (as determined by the Secretary), the  
11 United States Public Health Service may produce the product itself, or provide for  
12 the production of such product through a licensing arrangement.

#### 13 "ACCESS TO COMPANY INFORMATION

14 "Sec. 554. (a) Each tobacco product manufacturer shall establish  
15 procedures to ensure disclosure of material in compliance with this section.

16 "(b) In addition to any other disclosure obligations under this Act, the  
17 Tobacco Products Control Act of 1998, or any other law, each tobacco product  
18 manufacturer shall disclose to the Secretary all non-public research in its  
19 possession or control relating to the addiction or dependency, or the health or  
20 safety, of tobacco products, including (without limitation) all research relating to

1 processes to make tobacco products less hazardous or otherwise of reduced risk  
2 to consumers. The Secretary shall establish protections to ensure the  
3 confidentiality of any information submitted to the Secretary under this paragraph.

4 "(c) With respect to tobacco product manufacturers, the Secretary shall  
5 have the same access to records and information, inspection authority, and  
6 subpoena authority as is available with respect to manufacturers of other medical  
7 devices under this Act.

#### 8 "OVERSIGHT OF TOBACCO PRODUCT MANUFACTURING

9 "Sec. 555. The Secretary shall by regulation prescribe good manufacturing  
10 practice standards for tobacco products. Such regulations shall be modeled after  
11 good manufacturing practice regulations for medical devices, food, and other  
12 items under section 520(f) of this Act. Such standards shall be directed  
13 specifically toward tobacco products, and shall include —

14 "(1) A quality control system, to ensure that tobacco products comply  
15 with such standards.

16 "(2) A system for inspecting tobacco product materials to ensure their  
17 compliance with such standards.

18 "(3) Requirements for proper handling of finished tobacco products.

19 "(4) Strict tolerances for pesticide chemical residues in or on tobacco  
20 or tobacco product commodities in the possession of the manufacturer,

1 except that nothing in this subparagraph shall affect any authority of the  
2 Environmental Protection Agency.

3 “(5) Authority for officers or employees of the Secretary to inspect  
4 any factory, warehouse, or other establishment of any tobacco product  
5 manufacturer, and to have access to records, files, papers, processes,  
6 controls and facilities related to tobacco product manufacturing, in  
7 accordance with appropriate authority and rules promulgated under this  
8 Act.

9 “(6) A requirement that the tobacco product manufacturer maintain  
10 such files and records as the Secretary may specify, as well as that the  
11 manufacturer report to the Secretary such information as the Secretary  
12 shall require, in accordance with section 519.

13 “AUTHORITY OF THE SECRETARY

14 “Sec. 556. The Secretary may, by a rulemaking conducted under section  
15 553 of title 5, United States Code, revise any requirement of sections 545, 546,  
16 and 547 on and after the date which is 5 years after the date of enactment of this  
17 section, if the Secretary determines that such a revision would promote the  
18 reduction in the use of tobacco products. Nothing in this subchapter shall limit  
19 any other authority of the Secretary under this or any other law.

## "CIGARETTE TAR YIELDS

"Sec. 557. (a) In addition to the requirements for the establishment of a performance standard regarding tobacco product manufacturers provided in section 514(a)(3), no cigarette shall be sold in the United States which exceeds a 12 mg tar yield, using the testing methodology in effect and utilized by the Federal Trade Commission on June 20, 1997. Nothing in this paragraph shall be construed to limit the authority of the Secretary to require further reduction of the tar yields in tobacco products pursuant to this Act or any other provision of law.

"(b) Paragraph (a) shall take effect on the date which is three years after the date of enactment of this section."

## SUBTITLE D -- PENALTIES

### SEC. 131. PENALTIES

Section 307 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335b) is amended by adding at the end the following:

"(f) TOBACCO PRODUCT PENALTIES. — (1)(A) Any tobacco product manufacturer, or employee or agent of any tobacco product manufacturer, who violates this Act shall be subject to civil penalties provided in this Act. In addition, the Secretary may require any such manufacturer to include in its advertising for the relevant tobacco product a statement of such violation.

1       “(B) Any tobacco product manufacturer or employee or agent of any  
2 tobacco product manufacturer who fails to disclose to the Secretary research  
3 relating to the health effects of tobacco products and information regarding the  
4 toxicity of non-tobacco ingredients and constituents shall be subject to a civil  
5 penalty of not more than \$10,000,000 for each such violation. Such civil penalty  
6 shall be in addition to any other criminal, civil or administrative penalty prescribed  
7 by law.

8       “(2) The Secretary may commence a civil action to assess and recover any  
9 civil penalty under subparagraph (1) in the district court of the United States for  
10 the district in which the violation is alleged to have occurred or in which the  
11 defendant resides or has its principal place of business. The court shall have  
12 jurisdiction to assess a civil penalty in such an action. In determining the amount  
13 of any civil penalty to be assessed under this subsection, the court shall take into  
14 account the gravity of the violation, the economic benefit or savings (if any)  
15 resulting from the violation, the size of the violator's business, the violator's  
16 history of compliance with this Act, action taken to remedy the violation, the effect  
17 of the penalty on the violator's ability to continue business operations, and such  
18 other matters as justice may require. In any such action, subpoenas for  
19 witnesses who are required to attend a district court in any district may run into  
20 any other district.

1       “(3)(A) A State may commence a civil action to assess and recover any  
2 civil penalty under subparagraph (1) in the appropriate courts of the State in  
3 which the violation is alleged to have occurred. The court shall have jurisdiction  
4 to assess a civil penalty in such an action. In determining the amount of any civil  
5 penalty to be assessed under this subsection, the court shall take into account the  
6 gravity of the violation, the economic benefit or savings (if any) resulting from the  
7 violation, the size of the violator’s business, the violator’s history of compliance  
8 with this Act, action taken to remedy the violation, the effect of the penalty on the  
9 violator’s ability to continue business operations, and such other matters as  
10 justice may require.

11       “(B) No State may recover a penalty under clause (A) in an amount greater  
12 than those set forth in this section. No State may recover any such penalty if that  
13 penalty would be imposed for a violation for which a penalty has already been  
14 recovered under subparagraph (2).

15       “(C) ADD PROVISION REGARDING REMOVAL TO FEDERAL COURT.”.

16                   **TITLE II -- REDUCTIONS IN UNDERAGE TOBACCO USE**

**SUBTITLE A -- UNDERAGE USE**

**SEC. 201. GOALS FOR REDUCING UNDERAGE TOBACCO USE.**

(a) GOALS.-- As part of a comprehensive national tobacco control policy, the Secretary, working in cooperation with State and local governments and the private sector, shall take all actions under this Act necessary to ensure that the required percentage reductions in underage use of tobacco products set forth in this title are achieved.

(b) REQUIRED REDUCTIONS FOR CIGARETTES.-- With respect to cigarettes, the required percentage reductions in underage use, as set forth in section 202, mean--

| <u>Calendar Year After<br/>Date of Enactment</u> | <u>Required Percentage Reduction<br/>in Underage Cigarette Use</u> |
|--------------------------------------------------|--------------------------------------------------------------------|
| Years 5 and 6                                    | 30 percent reduction                                               |
| Years 7, 8 and 9                                 | 50 percent reduction                                               |
| Year 10 and thereafter                           | 60 percent reduction                                               |

(c) REQUIRED REDUCTIONS FOR SMOKELESS TOBACCO.-- With respect to smokeless tobacco products, the required percentage reductions in underage use, as set forth in section 202, mean--

Calendar Year After  
Date of Enactment

Required Percentage Reduction  
in Underage Smokeless Tobacco Use

Years 5 and 6

25 percent reduction

Years 7, 8 and 9

35 percent reduction

Year 10 and thereafter

45 percent reduction

**SEC. 202. LOOK-BACK ASSESSMENT.**

(a) DETERMINATION OF UNDERAGE USE.-- (1) Upon the conclusion of the fifth year after the date of enactment of this Act, and annually thereafter, the Secretary shall determine the percent incidence of underage use of cigarettes and smokeless tobacco by calculating the average, weighted by relative population of such age groups in 1995 as determined by the Bureau of the Census, of the percentages of individuals in grade 12 (ages 16 and 17), in grade 10 (ages 14 and 15), and in grade 8 (age 13) who used cigarettes or smokeless tobacco, as appropriate, on a daily basis during the preceding year. The percentages used in this calculation are to be those measured by (A) the University of Michigan survey, or (B) such comparable index using identical methodology as is chosen by the Secretary after notice and the opportunity for comment in accordance with section 553 of title 5, United States Code. If the methodology employed by the University of Michigan Survey is changed in a material manner from that employed from 1986 through 1996 (including by

1 changing the states or regions on which the University of Michigan Survey is  
 2 based), or is (in the opinion of the Secretary) no longer the best available data,  
 3 the Secretary shall use the percentages measured by an index chosen by the  
 4 Secretary, after notice and the opportunity for comment in accordance with  
 5 section 553 of title 5, United States Code, that has a methodology identical to that  
 6 employed by the University of Michigan Survey from 1986 through 1996. The  
 7 Secretary shall make the data on which the results of the University of Michigan  
 8 survey or such other comparable index are based available to the public upon  
 9 request.

10 (2) The Secretary shall impose a surcharge under subsection (b) on  
 11 cigarette manufacturers unless the Secretary determines pursuant to paragraph  
 12 (1) that the required percentage reduction applicable in that year was achieved.

13 (3) The Secretary shall impose a surcharge under subsection (c) on  
 14 smokeless tobacco product manufacturers unless the Secretary determines  
 15 pursuant to paragraph (1) that the required percentage reduction applicable in  
 16 that year was achieved.

17 (b) CALCULATION OF SURCHARGE APPLICABLE TO CIGARETTES.—  
 18 The Secretary shall calculate the surcharge applicable to cigarette manufacturers  
 19 to be imposed under this section by —

1 (1) determining the non-attainment percentage for cigarettes;

2 (2) if the non-attainment percentage for cigarettes is five percentage  
3 points or less, multiplying the non-attainment percentage for cigarettes by  
4 the per percentage point surcharge amount;

5 (3) if the non-attainment percentage for cigarettes is greater than five  
6 percentage points but not more than ten percentage points, (A) multiplying  
7 the number 5 by the per percentage point surcharge amount, and (B)  
8 adding the sum obtained by multiplying the number of percentage points by  
9 which the non-attainment percentage for cigarettes exceeds five by twice  
10 the per percentage point surcharge amount; and

11 (4) if the non-attainment percentage for cigarettes is greater than ten  
12 percentage points, (A) multiplying the number 5 by the percentage point  
13 surcharge amount, (B) adding the sum obtained by multiplying the number  
14 5 by twice the per percentage point surcharge amount, and (C) adding the  
15 sum obtained by multiplying the number of percentage points by which the  
16 non-attainment percentage exceeds ten by three times the per percentage  
17 point surcharge amount.

18 (c) CALCULATION OF SURCHARGE APPLICABLE TO SMOKELESS

19 TOBACCO.-- The Secretary shall calculate the surcharge applicable to

20 smokeless tobacco product manufacturers to be imposed under this section by —

1 (1) determining the non-attainment percentage for smokeless  
2 tobacco products;

3 (2) if the non-attainment percentage for smokeless tobacco products  
4 is five percentage points or less, multiplying the non-attainment  
5 percentage for smokeless tobacco products by the per percentage point  
6 surcharge amount;

7 (3) if the non-attainment percentage for smokeless tobacco products  
8 is greater than five percentage points but not more than ten percentage  
9 points, (A) multiplying the number 5 by the per percentage point surcharge  
10 amount, and (B) adding the sum obtained by multiplying the number of  
11 percentage points by which the non-attainment percentage for smokeless  
12 tobacco products exceeds five by twice the per percentage point surcharge  
13 amount; and

14 (4) if the non-attainment percentage for smokeless tobacco products  
15 is greater than ten percentage points, (A) multiplying the number 5 by the  
16 percentage point surcharge amount, (B) adding the sum obtained by  
17 multiplying the number 5 by twice the per percentage point surcharge  
18 amount, and (C) adding the sum obtained by multiplying the number of  
19 percentage points by which the non-attainment percentage exceeds ten by  
20 three times the per percentage point surcharge amount.

1 (d) OBLIGATION FOR SURCHARGE.-- (1) Any surcharge due and  
2 payable by cigarette manufacturers shall be the joint and several obligation of  
3 such manufacturers, allocated by actual market share.

4 (2) Any surcharge payable by smokeless tobacco product manufacturers  
5 will be the joint and several obligation of such manufacturers, allocated by actual  
6 market share.

7 (3) If the surcharges are allocated by market share, the Secretary shall  
8 make such allocations according to each manufacturer's share of the domestic  
9 cigarette or smokeless tobacco market, as appropriate, in the year for which the  
10 surcharge is being assessed, based on actual Federal excise tax payments.

11 (e) METHOD OF SURCHARGE ASSESSMENT.-- The Secretary shall  
12 assess a surcharge for a specific year on or before May 1 of the subsequent  
13 calendar year. Surcharge payments shall be paid on or before July 1 of the year  
14 in which they are assessed. The Secretary may establish, by regulation, interest  
15 at a rate up to 3 times the prevailing prime rate at the time the surcharge is  
16 assessed, and additional charges in an amount up to 3 times the surcharge for  
17 late payment of the surcharge.

18 (f) INJUNCTIVE RELIEF.-- No stay or other injunctive relief enjoining  
19 assessment and collection of the surcharge amounts pending appeal or otherwise  
20 may be granted by the Secretary or any court.

1 (g) TRANSFER OF SURCHARGE TO STATES.-- (1) The Secretary shall  
2 transfer 90 percent of all surcharges paid, without further appropriation, as grants  
3 to State and local government public health agencies for additional efforts by  
4 State and local government agencies (including by contract between such  
5 agencies and private entities) to reduce further the use of tobacco products by  
6 persons under the age of 18 years.

7 (2) The Secretary may retain up to 10 percent of all surcharges paid and  
8 not refunded to pay the costs of administration of this subtitle. If the costs of  
9 administration of this subtitle are less than 10 percent of all surcharges paid, the  
10 Secretary may —

11 (A) transfer any portion of the excess to other Federal  
12 agencies, or to State and local government agencies, for the purpose  
13 of reducing further underage tobacco use; or

14 (B) expend such amounts directly for the purpose of reducing  
15 further underage tobacco use.

16 (h) BUSINESS EXPENSE DEDUCTION.— Any surcharge paid by a  
17 tobacco product manufacturer under this section shall not be deductible as an  
18 ordinary and necessary business expense or otherwise under title 26, United  
19 States Code.

**SEC. 203. DEFINITIONS.**

As used in this subtitle —

(1) The term "base excess underage cigarette use population" for a specific year means the product of the non-attainment percentage for cigarettes in that year multiplied by the total underage population in that year.

(2) The term "base excess underage smokeless tobacco use population" for a specific year means the product of the non-attainment percentage for smokeless tobacco products in that year multiplied by the total underage population in that year.

(3) The term "base incidence percentage" means —

(A) in the case of cigarettes, the average, weighted by relative population of the following age groups in 1995 as determined by the Bureau of the Census, of (i) the average of the percentages of individuals in grade 12 (ages 16 and 17) from 1986 to 1996 who used cigarettes on a daily basis; (ii) the average of the percentages of individuals in grade 10 (ages 14 and 15) from 1991 to 1996 who used cigarettes on a daily basis; and (iii) the average of the percentages of individuals in grade 8 (age 13) from 1991 to 1996 who used cigarettes on a daily basis; and

(B) in the case of smokeless tobacco products, the average, weighted by relative population of the following age groups in 1995 as determined by the Bureau of the Census, of the percentage of individuals in grade 12 (ages 16 and 17), individuals in grade 10 (ages 14 and 15), and individuals in grade 8 (age 13) who used smokeless tobacco products on a daily basis in 1996.

The percentages specified in this subparagraph are those measured by the University of Michigan Survey or by such comparable index using identical methodology as is chosen by the Secretary after notice and the opportunity for comment in accordance with section 553 of title 5, United States Code.

(4) The term "cigarette manufacturers" means manufacturers of cigarettes sold in the United States.

(5) The term "inflation" refers to [Fill in/same as elsewhere in Act?].

(6) The term "non-attainment percentage for cigarettes" means the number of percentage points yielded by —

(A) in a year in which the percent incidence of underage use of cigarettes is less than the base incidence percentage, subtracting —

(i) the percentage by which the percent incidence of underage use of cigarettes in that year is less than the base incidence percentage, from

1 (ii) the required percentage reduction applicable in that

2 year; and

3 (B) in a year in which the percent incidence of underage use of  
4 cigarettes is greater than the base incidence percentage, adding —

5 (i) the percentage by which the percent incidence of  
6 underage use of cigarettes in that year is greater than the base  
7 incidence percentage, and

8 (ii) the required percentage reduction applicable in that  
9 year.

10 (7) The term "non-attainment percentage for smokeless tobacco  
11 products" means the number of percentage points yielded by —

12 (A) in a year in which the percent incidence of underage use of  
13 smokeless tobacco products is less than the base incidence  
14 percentage, subtracting —

15 (i) the percentage by which the percent incidence of  
16 underage use of smokeless tobacco products in that year is  
17 less than the base incidence percentage, from

18 (ii) the required percentage reduction applicable in that  
19 year; and

(B) in a year in which the percent incidence of underage use of smokeless tobacco products is greater than the base incidence percentage, adding —

(i) the percentage by which the percent incidence of underage use of smokeless tobacco products in that year is greater than the base incidence percentage; and

(ii) the required percentage reduction applicable in that year.

(8) The term “per percentage point surcharge amount” means —

(A) \$80 million in the case of cigarettes, as adjusted proportionately for —

(i) percentage increases or decreases compared with 1995 in the total underage population; and

(ii) percentage increases or decreases compared with 1996 in the average operating profit per cigarette unit

(measured in cents and weighted by annual sales) earned by cigarette manufacturers. The average operating profit per cigarette unit earned by cigarette manufacturers in 1996 shall be derived from the operating profit of cigarette manufacturers as reported to the Securities and Exchange Commission. The

average operating profit per unit earned by cigarette manufacturers for the year in which the surcharge is being determined shall be calculated and certified to the Secretary by a major, nationally recognized accounting firm with no connection to the tobacco industry retained by the Secretary, using the same methodology as employed in deriving the average operating profit per unit earned by cigarette manufacturers in 1996; and

(B) \$\_\_\_ in the case of smokeless tobacco products, as adjusted proportionately for —

(i) percentage increases or decreases compared with 1995 in the total underage population; and

(ii) percentage increases or decreases compared with 1996 in the average operating profit per smokeless tobacco unit (measured in cents and weighted by annual sales) earned by smokeless tobacco product manufacturers. The average operating profit per smokeless tobacco unit earned by smokeless tobacco product manufacturers in 1996 shall be derived from the operating profit of smokeless tobacco product manufacturers as reported to the Securities and Exchange

Commission. The average operating profit per unit earned by smokeless tobacco product manufacturers for the year in which the surcharge is being determined shall be calculated and certified to the Secretary by a major, nationally recognized accounting firm with no connection to the tobacco industry retained by the Secretary, using the same methodology as employed in deriving the average operating profit per unit earned by smokeless tobacco product manufacturers in 1996.

(9) The term "required percentage reduction" means —

(A) in the case of cigarettes, a 30 percent reduction in underage use of cigarettes from the base incidence percentage in the fifth and sixth years after the date of enactment of this Act; a 50 percent reduction in underage use of cigarettes from the base incidence percentage in the seventh, eighth and ninth years after such date; and a 60 percent reduction in underage use of cigarettes from the base incidence percentage in each year beginning with the tenth year after such date; and

(B) in the case of smokeless tobacco products, a 25 percent reduction in underage use of smokeless tobacco products from the base incidence percentage in the fifth and sixth years after such

1 date; a 35 percent reduction in underage use of smokeless tobacco  
2 products from the base incidence percentage in the seventh, eighth  
3 and ninth years after such date; and a 45 percent reduction in  
4 underage use of smokeless tobacco products from the base  
5 incidence percentage in each year beginning with the tenth year after  
6 such date.

7 (10) The term "smokeless tobacco product manufacturers" means  
8 manufacturers of smokeless tobacco products sold in the United States.

9 (11) The term "total underage population" means the total number of  
10 persons aged 13 through 17, inclusive, resident in the United States.

11 (12) The term "University of Michigan Survey" means the University  
12 of Michigan's National High School Drug Use Survey entitled, "Monitoring  
13 the Future".

**SUBTITLE B — STATE ENFORCEMENT INCENTIVES**

**SEC. 211. STATE ENFORCEMENT INCENTIVES.**

(a) **RELEVANT LAW.**— Section 300x-26(a)(1) and (2) of title 42, United States Code, is amended by striking “section 300x-21 of this title” and inserting in lieu thereof “section \_\_\_\_ of title \_\_\_\_, United States Code,”.

(b) **ENFORCEMENT.**— Section 300x-26(b)(1) of title 42, United States Code, is amended by striking “section 300x-21 of this title” and inserting in lieu thereof “section \_\_\_\_ of title \_\_\_\_, United States Code,”.

(c) **ACTIVITIES AND REPORTS.**— Section 300x-26(b)(2) of title 42, United States Code, is amended to read as follows:

“(2) Activities and reports regarding enforcement

“For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section \_\_\_\_ of title \_\_\_\_, United States Code, is that the State involved will —

(A) monthly conduct random, unannounced inspections of sales or distribution outlets in the State to ensure compliance with the law described in subsection (a) of this section;

“(B) annually submit to the Secretary a report describing —

1                   “(i) the activities carried out by the State to enforce such  
2 law during the fiscal year preceding the fiscal year for which  
3 the State is seeking the grant;

4                   “(ii) the extent of success the State has achieved in  
5 reducing the availability of tobacco products to individuals  
6 under the age of 18 years; and

7                   “(iii) the strategies to be utilized by the State for  
8 enforcing such law during the fiscal year for which the grant is  
9 sought; and

10                  “(C)(i) a detailed description of the activities carried out by the  
11 State and its political subdivisions to enforce the law described in  
12 subsection (a) of this section during the fiscal year preceding the  
13 fiscal year for which the State is seeking the grant;

14                  “(ii) a detailed description of the extent of success the State  
15 has achieved in reducing the availability of tobacco products to  
16 individuals under the age of 18 years, including detailed statistical  
17 results of the inspections described in subparagraph (A) of this  
18 paragraph;

19                  “(iii) a detailed description of how the inspections described in  
20 subparagraph (A) were conducted and the methods used to identify

1 outlets, with appropriate protection for the confidentiality of  
2 information regarding the timing of inspections and other  
3 investigative techniques whose effectiveness depends on continued  
4 confidentiality;

5 “(iv) the strategies to be utilized by the State for enforcing the  
6 law described in subsection (a) of this section during the fiscal year  
7 for which the grant is sought; and

8 “(v) the identity of the single State agency designated by the  
9 Governor of the State to be responsible for the implementation of the  
10 requirements of this section.

11 Inspections conducted under this paragraph shall include at least 250  
12 random, unannounced inspections of retail sale outlets annually for each  
13 1,000,000 persons resident in the State, as most recently determined by  
14 the Bureau of the Census. Such inspections shall cover a range of outlets  
15 (not preselected on the basis of prior violations) to measure overall levels  
16 of compliance as well as to identify violations, and shall be conducted to  
17 provide a probability sample of outlets. The sample must reflect the  
18 distribution of the population under the age of 18 years throughout the  
19 State and the distribution of the outlets throughout the State accessible to  
20 youth. Indian tribes shall conduct such inspections monthly of at least 10

1 percent of the retail outlets subject to their jurisdiction. Except as provided  
 2 in this paragraph, any reports required by this paragraph shall be made  
 3 public. As used in this paragraph, the term 'outlet' refers to any location  
 4 that sells at retail or otherwise distributes tobacco products to consumers,  
 5 including to locations that sell such products over-the-counter."

6 (d) NONCOMPLIANCE.—Section 300x-26(c) of title 42, United States  
 7 Code, is amended as follows:

8 (1) Strike "section 300x-21 of this title" and insert in lieu thereof  
 9 "section \_\_\_\_ of title \_\_\_\_\_, United States Code,".

10 (2) After the first sentence, insert the following: "The Secretary shall  
 11 find that the State is not in compliance with such subsections unless the  
 12 State has complied with such subsections and has pursued all reasonably  
 13 available measures to enforce the law described in subsection (a) of this  
 14 section. A State shall be considered to have pursued all reasonably  
 15 available measures to enforce the law described in subsection (a) of this  
 16 section if the inspections described in subsection (b) of this section result in  
 17 a compliance rate in such State of at least 75 percent in the fifth and sixth  
 18 fiscal years after the date of enactment of the Tobacco Products Control  
 19 Act of 1977, at least 85 percent in the seventh, eighth and ninth fiscal years

1 after such date, and at least 90 percent in every fiscal year beginning with  
2 the tenth fiscal year after such date."

3 (3) Amend the second sentence to read as follows: "If, after notice to  
4 the State, the Secretary concludes that the State is not in compliance with  
5 subsections (a) and (b) of this section, the Secretary shall provide for a  
6 reduction in the amount of the allotment under section \_\_\_\_ of title \_\_\_\_,  
7 United States Code, for the fiscal year involved by, in the case of the first  
8 applicable fiscal year and the first three fiscal years following such  
9 applicable fiscal year, \_\_\_\_; and in the case of all subsequent fiscal  
10 years, its allotment for each percentage point by which the compliance rate  
11 in such State resulting from the inspections described in subsection (b) of  
12 this section falls short of the target compliance rate for such fiscal year  
13 described in this subsection, or 20 percent of such allotment, whichever is  
14 less."

15 ALTERNATIVE LANGUAGE:

16 (3) Amend the second sentence to read as follows: "If, after notice to  
17 the State, the Secretary concludes that the State is not in compliance with  
18 subsections (a) and (b) of this section, the Secretary shall publish in the  
19 Federal Register a notice of such noncompliance, together with data  
20 regarding the extent of such noncompliance."

(4) Insert after the second sentence the following: "Upon completion of any proceedings under subsection (e) of this section, the Secretary shall order the reallocation of any amounts withheld from a State under this subsection to those States with the best record of compliance with subsections (a) and (b) of this section. Such reallocations shall be made in amounts and pursuant to a formula to be determined by the Secretary."

ALTERNATIVE LANGUAGE:

(4) Insert after the second sentence the following: "Upon completion of any proceedings under subsection (e) of this section, the Secretary shall publish in the Federal Register a notice which orders the reallocation of any amounts withheld from a State under this subsection to those States with the best record of compliance with subsections (a) and (b) of this section. Such reallocations shall be made in amounts and pursuant to a formula to be determined by the Secretary."

(e) DEFINITION.—Section 300x-26(d) of title 42, United States Code, is amended to read as follows:

"(d) For the purposes of this section, the term 'first applicable fiscal year' means \_\_\_\_\_."

(f) RELEASE AND DISBURSEMENT.—Section 300x-26 of title 42, United States Code, is amended by adding at the end the following:

1       “(e)(1) Upon notice from the Secretary that a reduction in allotment has  
2       been ordered pursuant to subsection (c) of this section, a State may petition the  
3       Secretary for a release and disbursement of up to 75 percent of the amount  
4       withheld, and shall give timely written notice of such petition to the attorney  
5       general of that State and to all tobacco product manufacturers.

6       “(2) The agency shall conduct a hearing on such a petition, in which the  
7       attorney general of the State and tobacco product manufacturers may participate  
8       and be heard.

9       “(3) The burden shall be on the State to prove, by a preponderance of the  
10      evidence, that the release and disbursement should be made. The Secretary's  
11      decision on whether to grant such a release, and the amount of any such  
12      disbursement, shall be based on whether —:

13               “(A) the State has acted in good faith and in full compliance  
14              with this Act and any rules or regulations promulgated under this  
15              Act;

16               “(B) the State has pursued all reasonably available measures  
17              to attain the compliance rates and required percentage reductions  
18              applicable in the year for which the release is being sought;

19               “(C) there is evidence of any direct or indirect action by the  
20              State to undermine the achievement of the compliance rates, the

1 required percentage reductions, or other terms and objectives of this  
2 Act or the Tobacco Products Control Act of 1998; and

3 "(D) any other relevant evidence.

4 "(4) A State shall be entitled to interest on any withheld amount released at  
5 the average United States 52-Week Treasury Bill rate for the period between the  
6 withholding of the amount and its release.

7 "(5) Any State attorney general or tobacco product manufacturer aggrieved  
8 by a final decision on a petition filed under this subsection may seek judicial  
9 review of such decision within 30 days in the United States Court of Appeals for  
10 the District of Columbia Circuit. Unless otherwise specified in this Act, judicial  
11 review under this section shall be governed by sections 701 through 706 of title 5,  
12 United States Code.

13 "(6) No stay or other injunctive relief enjoining a reduction in a State's  
14 allotment pending appeal or otherwise may be granted by the Secretary or any  
15 court."

**TITLE III — TOBACCO PRODUCT WARNINGS AND**

**SMOKE CONSTITUENT DISCLOSURE**

**SUBTITLE A — PRODUCT WARNINGS, LABELING AND PACKAGING**

**SEC. 301. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

**"Labeling**

"Sec. 4. (a)(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

"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.

1       “WARNING: Quitting smoking now greatly reduces serious risks to your  
2       health.

3       “(2)(A) Each label statement required by paragraph (1) shall be located in  
4       the upper portion of the front panel of the package. Except as provided in  
5       subparagraph (B), each label statement shall comprise at least the top 25 percent  
6       of the front panel of the package. The phrase ‘WARNING’ shall appear in capital  
7       letters and all text shall be in 17-point type, unless the text of the label statement  
8       would occupy more than 70 percent of such area, in which case the text may be  
9       in a smaller type size, provided that at least 60 percent of such area is occupied  
10      by required text. The text shall be black on a white background, or white on a  
11      black background, in an alternating fashion pursuant to the plan submitted under  
12      subsection (b)(4).

13      “(B) For any cigarette brand package which employs a flip-top style (if such  
14      packaging was used for that brand in commerce prior to June 21, 1997), the label  
15      statement required by paragraph (1) shall be located on the flip-top area of the  
16      package, even if such area is less than 25 percent of the area of the front panel.  
17      Except as provided in this paragraph, the provisions of this subsection shall apply  
18      to such packages.

1       “(3) The provisions of this subsection do not apply to a distributor or retailer  
2 of cigarettes which does not manufacture, package, or import cigarettes for sale  
3 or distribution within the United States.

4       “(b)(1) It shall be unlawful for any manufacturer or importer of cigarettes to  
5 advertise or cause to be advertised within the United States any cigarette unless  
6 its advertising bears, in accordance with the requirements of this section, one of  
7 the labels specified in subsection (a) of this section.

8       “(2) Each label statement required by subsection (a) of this section in  
9 cigarette advertising shall comply with the standards set forth in this paragraph.  
10 For press and poster advertisements, each such statement and (where  
11 applicable) any required statement relating to tar, nicotine, or other constituent  
12 yield shall comprise 20 percent of the area of the advertisement. Such area shall  
13 be delineated by a dividing line of contrasting color from the advertisement. The  
14 Secretary may revise the required type sizes in such area in such manner as the  
15 Secretary determines appropriate. The text of any such statements shall be  
16 required to appear only within the 20 percent area required by this paragraph.  
17 The phrase ‘WARNING’ shall appear in capital letters, and each label statement  
18 shall appear in conspicuous and legible type. The text of the label statement  
19 shall be black on a white background, or white on a black background, in an  
20 alternating fashion pursuant to the plan submitted under paragraph (4) of this

1 subsection. The text of such label statements shall be in a typeface pro rata to  
2 the following requirements: 45-point type for a whole-page broadsheet  
3 newspaper advertisement; 39-point type for a half-page broadsheet newspaper  
4 advertisement; 39-point type for a whole-page tabloid newspaper advertisement;  
5 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for  
6 a DPS magazine or whole-page magazine advertisement; 22.5-point type for a 28  
7 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2  
8 column advertisement.

9 “(3) The Secretary shall have authority through a rulemaking under section  
10 553 of title 5, United States Code, to revise the format and type sizes for the label  
11 statements required by this section or the text, format and type sizes of any  
12 required tar, nicotine yield or other constituent disclosures, or to establish the  
13 text, format and type sizes for any other disclosures required under the Federal  
14 Food, Drug, and Cosmetic Act (21 U.S.C. 321 et. seq.). The text of any such  
15 label statements or disclosures shall be required to appear only within the 20  
16 percent area of cigarette advertisements provided by paragraph (2) of this  
17 subsection. The Secretary shall promulgate regulations which provide for  
18 adjustments in the format and type sizes of any text required to appear in such  
19 area to ensure that the total text required to appear by law will fit within such  
20 area.

1       “(4) The label statements required by subsection (a) of this section shall be  
2       rotated by each manufacturer of cigarettes on each brand of cigarettes in  
3       accordance with a plan submitted by the manufacturer or importer and approved  
4       by the Secretary. Each such plan shall provide for an approximately even  
5       distribution of the labels among the packages of each brand style of the  
6       cigarettes produced by each manufacturer for each year.

7       “(5) The label statements required by subsection (b) of this section in  
8       advertisements shall be rotated by each manufacturer or importer of cigarettes  
9       quarterly in alternating sequence for each brand of cigarettes manufactured by  
10      the manufacturer or importer, in accordance with a plan submitted by the  
11      manufacturer or importer and approved by the Secretary.”.

12      **SEC. 302. AUTHORITY TO REVISE CIGARETTE WARNING LABEL**  
13      **STATEMENTS.**

14      Section 4 of the Federal Cigarette Labeling and Advertising Act ( 15 U.S.C.  
15      1333), as amended by section 301 of this title, is further amended by adding at  
16      the end the following:

17      “(c) The Secretary may, by a rulemaking conducted under section 553 of  
18      title 5, United States Code, revise the text of any of the warning label statements  
19      required by subsection (a) of this section if the Secretary determines that such a

1 change would promote greater public understanding of the risks associated with  
2 the use of tobacco products.

3 “(d) It shall be unlawful for any person to manufacture, package, or import  
4 for sale or distribution within the United States any cigarettes the package of  
5 which fails to bear the Statement of Intended Use required by the Secretary and  
6 specified in section 897.25 of title 21, Code of Federal Regulations (21 CFR  
7 897.25) as in effect on the date of enactment of the Tobacco Products Control Act  
8 of 1998.”

9 **SEC. 303. SMOKELESS TOBACCO LABELS AND ADVERTISING**

10 **WARNINGS.**

11 Section 3 of the Comprehensive Smokeless Tobacco Health Education Act  
12 of 1986 (15 U.S.C. 4402) is amended to read as follows:

13 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

14 **“(a) GENERAL RULE. —** (1) It shall be unlawful for any person to  
15 manufacture, package, or import for sale or distribution within the United States  
16 any smokeless tobacco product unless the product package bears, in accordance  
17 with the requirements of this Act, one of the following labels:

18 **“WARNING:** This product can cause mouth cancer.

19 **“WARNING:** This product can cause gum disease and tooth loss.

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

2 "WARNING: Smokeless tobacco is addictive.

3 "(2) Each label statement required by paragraph (1) shall be

4 "(A) located on the principal display panel of the package, and  
5 each label statement shall comprise at least 25 percent of such  
6 display panel; and

7 "(B) in 17-point type and in black text on a white background,  
8 or white text on a black background, in an alternating fashion  
9 pursuant to the plan submitted under subsection (b)(3): *Provided,*  
10 That, if the text of a label statement would occupy more than 70  
11 percent of the area specified by subparagraph (A), such text may  
12 appear in a smaller type size, so long as at least 60 percent of such  
13 warning areas occupied by the label statement.

14 "(3) The label statements required by paragraph (1) shall be introduced by  
15 each manufacturer, packager, or importer of smokeless tobacco products  
16 concurrently into the distribution chain of such products.

17 "(4) The provisions of this subsection do not apply to a distributor or retailer  
18 of any smokeless tobacco product which does not manufacture, package, or  
19 import smokeless tobacco products for sale or distribution within the United  
20 States.

1       “(b) REQUIRED LABELS. — (1) It shall be unlawful for any manufacturer,  
2 packager, or importer of smokeless tobacco products to advertise or cause to be  
3 advertised within the United States any smokeless tobacco product unless its  
4 advertising bears, in accordance with the requirements of this section, one of the  
5 labels specified in subsection (a).

6       “(2) Each label statement required by subsection (a) in smokeless tobacco  
7 advertising shall comply with the standards set forth in this paragraph. For press  
8 and poster advertisements, each such statement and (where applicable) any  
9 required statement relating to tar, nicotine, or other constituent yield shall —

10               “(A) comprise at least 20 percent of the area of the  
11 advertisement, and the warning area shall be delineated by a  
12 dividing line of contrasting color from the advertisement; and

13               “(B) the phrase ‘WARNING’ shall appear in capital letters and  
14 each label statement shall appear in conspicuous and legible type.

15       The text of the label statement shall be black on a white background,  
16 or white on a black background, in an alternating fashion pursuant to  
17 the plan submitted under paragraph (3).

18       “(3) The label statements required by subsection (a) shall be rotated by  
19 each manufacturer, packager, or importer of smokeless tobacco products  
20 quarterly in the advertisements for each brand of smokeless tobacco products in

1 accordance with a plan submitted by the manufacturer, packager, or importer and  
2 approved by the Secretary.

3 “(c) REQUIRED PACKAGE STATEMENT. — It shall be unlawful for any  
4 person to manufacture, package, or import for sale or distribution within the  
5 United States any smokeless tobacco products the package of which fails to bear  
6 the Statement of Intended Use required by the Secretary and specified in section  
7 897.25 of title 21, Code of Federal Regulations (21 CFR 897.25) as in effect on  
8 the date of enactment of the Tobacco Products Control Act of 1998. Such  
9 Statement of Intended Use shall appear on the side of the package of the  
10 smokeless tobacco product.”.

11 **SEC. 304. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT**  
12 **WARNING LABEL STATEMENTS.**

13 Section 3 of the Comprehensive Smokeless Tobacco Health Education Act  
14 of 1986 (15 U.S.C. 4402) as amended by section 303 of this title, is further  
15 amended by adding at the end the following:

16 “(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS. — The  
17 Secretary may, by a rulemaking conducted under section 553 of title 5, United  
18 States Code, revise the format, type size and text of any of the warning label  
19 statements required by subsection (a) of this section, or establish the format, type

1 size and text of any other disclosures required under the Federal Food, Drug, and  
2 Cosmetic Act (21 U.S.C. 321 et seq.), if the Secretary finds that such a change  
3 would promote greater public understanding of the risks associated with the use  
4 of smokeless tobacco products.”.

5 **SEC. 305. TAR, NICOTINE AND OTHER SMOKE CONSTITUENT**

6 **DISCLOSURE TO THE PUBLIC.**

7 Section 4(a) of the Federal Cigarette Labeling and Advertising Act (15  
8 U.S.C. 1333 (a)), as amended by section 301 of this title, is further amended by  
9 adding at the end the following:

10 “(4)(A) The Secretary shall, by a rulemaking conducted under section 553  
11 of title 5, United States Code, determine (in the Secretary’s sole discretion)  
12 whether cigarette and other tobacco product manufacturers shall be required to  
13 include in the area of each cigarette advertisement specified by subsection (b) of  
14 this section, or on the package label, or both, the tar and nicotine yields of the  
15 advertised or packaged brand. Any such disclosure shall be in accordance with  
16 the methodology established pursuant to such regulations, shall conform to the  
17 type size requirements of subsection (b) of this section, and shall appear within  
18 the area specified in subsection (b) of this section.

1           “(B) Prior to the effective date of regulations promulgated under  
2 subparagraph (A) of this paragraph, manufacturers shall continue to report tar  
3 and nicotine yields in accordance with such requirements as are established by  
4 the Federal Trade Commission. After the effective date of the regulations issued  
5 pursuant to subparagraph (A) of this paragraph, the Federal Trade Commission  
6 shall have no authority regarding the disclosure of cigarette constituents.

7           “(C) In addition to the disclosures required by subparagraph (A) of this  
8 paragraph, the Secretary may, pursuant to a rulemaking conducted under section  
9 553 of title 5, United States Code, prescribe disclosure requirements regarding  
10 the level of any cigarette or other tobacco product smoke constituent. Any such  
11 disclosure may be required if the Secretary determines that disclosure would be  
12 of benefit to the public health, or otherwise would increase consumer awareness  
13 of the health consequences of the use of tobacco products, except that no such  
14 prescribed disclosure shall be required on the face of any cigarette package or  
15 advertisement. Nothing in this section shall prohibit the Secretary from requiring  
16 such prescribed disclosure through a cigarette or other tobacco product package  
17 or advertisement insert, or by any other means pursuant to the Federal Food,  
18 Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).”.

19                           **SUBTITLE B—TESTING AND REPORTING OF**

## TOBACCO PRODUCT SMOKE CONSTITUENTS

### SEC. 311. REGULATION REQUIREMENT.

(a) TESTING, REPORTING, AND DISCLOSURE.— Not later than 12 months after the date of enactment of this Act, the Secretary, through the Commissioner of the Food and Drug Administration, shall promulgate regulations under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) that meet the requirements of subsection (b) of this section.

(b) CONTENTS OF RULES.— The rules promulgated under subsection (a) of this section shall require the testing, reporting and disclosure of tobacco product smoke constituents and ingredients that the Secretary determines should be disclosed to the public in order to protect the public health. Such constituents shall include tar, nicotine, carbon monoxide and such other smoke constituents or ingredients as the Secretary may determine to be appropriate. The rule may require that manufacturers, packagers or importers make such disclosures relating to tar and nicotine through labels or advertising, and make such disclosures regarding other smoke constituents or ingredients as the Secretary determines are necessary to protect the public health.

(c) TRANSFER OF AUTHORITY.— Any authority of the Federal Trade Commission to conduct or to require the testing, reporting or disclosure of

- 1 tobacco product smoke constituents is transferred to the Food and Drug
- 2 Administration on the date on which regulations promulgated under subsection (a)
- 3 of this section take effect.

**TITLE IV — TOBACCO INDUSTRY COMPLIANCE AND EMPLOYEE  
PROTECTION FROM REPRISALS**

**SEC. 401. CORPORATE COMPLIANCE.**

(a) **REQUIRED PLAN.**-- Each tobacco product manufacturer shall establish and implement throughout its corporate operations a plan that meets the requirements of subsection (b) of this section. Each such plan shall be reviewed annually by the manufacturer, which shall take such action after the review as may be necessary to ensure the plan complies with this section.

(b) **ELEMENTS OF PLAN.**-- (1) Each plan established under this section shall contain elements that will --

(A) ensure compliance with this Act, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.), and regulations promulgated under such Acts, other applicable laws and regulations, and any order of a court;

(B) establish methods of achieving the goals of reduced access to and consumption of tobacco products by individuals under the age of 18 years, which shall provide incentives for achieving such goals within the corporate operations of the manufacturer; and

1 (C) provide incentives within the corporate operations of the manufacturer  
2 to develop products with reduced risk.

3 (2) Each such plan shall contain elements which are designed specifically  
4 to ensure compliance with Federal and State laws and regulations that make it  
5 unlawful to sell tobacco products to individuals under the age of 18 years, and  
6 other laws and regulations directed toward the use of tobacco products by  
7 individuals under the age of 18 years. To ensure compliance with such laws and  
8 regulations, each such plan shall also include --

9 (A) compliance standards and procedures to be followed by employees  
10 and agents of the manufacturer that are reasonably capable of eliminating or  
11 reducing the prospect of violations of such laws and regulations;

12 (B) assignment to a specific high-level employee of the manufacturer of the  
13 responsibility to oversee compliance with relevant standards and procedures  
14 directed toward preventing the use of tobacco products by individuals under the  
15 age of 18 years,

16 (C) requirements that tobacco product manufacturers exercise due care not  
17 to delegate substantial discretionary authority to employees or agents whom such  
18 manufacturer knows, or should know through the exercise of due diligence, would  
19 have a propensity to disregard such plan;

1 (D) training programs, publications, and other methods to communicate  
2 relevant standards and procedures under such plan to all employees and other  
3 agents of the manufacturer (including any person engaged in lobbying activities  
4 on behalf of the manufacturer);

5 (E) internal audits, specific telephone numbers for reporting violations or  
6 potential violations of such plan, and other measures to promote compliance with  
7 the plan;

8 (F) standards and procedures for disciplining employees and agents who  
9 violate such plan; and

10 (G) reasonable measures for responding to any violation of such plan, as  
11 well as to prevent similar violations of such plan.

12 (c) **ADDITIONAL REQUIREMENTS.**— In addition to compliance with  
13 specific provisions of law, each tobacco product manufacturer shall take  
14 additional measures to carry out the purposes of this Act, including—

15 (1) the promulgation of corporate principles that state and explain  
16 such manufacturer's commitment to compliance with applicable provisions  
17 of law, reductions in the use of tobacco products by individuals under the  
18 age of 18 years, and the development of tobacco products that present a  
19 reduced risk to public health;

1 (2) assignment to specific high-level employees of such  
2 manufacturer of the responsibility to promote efforts to achieve such  
3 principles; and

4 (3) reports to shareholders on compliance with applicable provisions  
5 of law and such plan, as well as progress toward meeting such principles.

6 (d) COOPERATION WITH RETAILERS.— Each tobacco product  
7 manufacturer shall undertake cooperative efforts with retail organizations to  
8 promote compliance with such principles. Such efforts may include inquiries into  
9 the level of compliance, as well as financial incentives for compliance, with such  
10 principles.

11 (e) PENALTY.— Any tobacco product manufacturer which violates this  
12 section shall be subject to a civil penalty of \$25,000 per day of violation. In  
13 addition, the Secretary may require any such manufacturer to include in its  
14 advertising for the relevant tobacco product a statement of such violation.

15 **SEC. 402. TOBACCO PRODUCT MANUFACTURER EMPLOYEE PROTECTION.**

16 (a) PROHIBITED ACTS.— No tobacco product manufacturer may  
17 discharge, demote or otherwise discriminate against any employee with respect  
18 to his or her compensation, terms, conditions, benefits, or privileges of  
19 employment because the employee (or any person acting pursuant to a request  
20 of the employee) —

1 (1) notified the manufacturer, the Commissioner of Food and Drugs,  
2 or any Federal, State or local public health or law enforcement authority of  
3 an alleged violation of this or any other Act;

4 (2) refused to engage in any practice made unlawful by such Acts, if  
5 the employee has identified the alleged illegality to the manufacturer;

6 (3) testified before Congress or at any Federal or State proceeding  
7 regarding any provision (or proposed provision) of such Acts;

8 (4) commenced, caused to be commenced, or is about to commence  
9 or cause to be commenced a proceeding under such Acts, or a proceeding  
10 for the administration or enforcement of any requirement imposed under  
11 such Acts;

12 (5) testified or is about to testify in any such proceeding; or

13 (6) assisted or participated, or is about to assist or participate, in any  
14 manner in such a proceeding or in any other manner in such a proceeding  
15 or in any other action to carry out the purposes of such Acts.

16 (b) EMPLOYEE COMPLAINT.— (1) Any employee of a tobacco product  
17 manufacturer who believes that he or she has been discharged, demoted or  
18 otherwise discriminated against by any person in violation of subsection (a) of  
19 this section may, within 180 days after such violation occurs, file (or have any  
20 person file on his or her behalf) a complaint with the Secretary alleging such

1 discharge, demotion or discrimination. Upon receipt of such a complaint, the  
2 Secretary shall notify the person named in the complaint of its filing.

3 (2)(A) Upon receipt of a complaint under paragraph (1) of this subsection,  
4 the Secretary shall conduct an investigation of the violation alleged in the  
5 complaint. Within 30 days after the receipt of such complaint, the Secretary shall  
6 complete such investigation and shall notify in writing the complainant (and any  
7 person acting in his or her behalf) and the person alleged to have committed such  
8 violation of the results of the investigation conducted pursuant to this paragraph.  
9 Within 90 days after the receipt of such complaint, the Secretary shall (unless the  
10 proceeding on the complaint is terminated by the Secretary on the basis of a  
11 settlement entered into by the Secretary and the person alleged to have  
12 committed such violation) issue an order either providing the relief prescribed in  
13 subparagraph (B) of this paragraph or denying the complaint. An order of the  
14 Secretary shall be made on the record after notice and the opportunity for a  
15 hearing in accordance with sections 554 and 556 of title 5, United States Code.  
16 Upon the conclusion of such a hearing and the issuance of a recommended  
17 decision that the complaint has merit, the Secretary shall issue a preliminary  
18 order providing the relief prescribed in subparagraph (B) of this paragraph, but  
19 may not order compensatory damages pending a final order. The Secretary may

1 not enter into a settlement terminating a proceeding on a complaint without the  
2 participation and consent of the complainant.

3 (B) If, in response to a complaint under paragraph (1) of this subsection,  
4 the Secretary determines that a violation of this paragraph has occurred, the  
5 Secretary shall order the person who committed such violation to (i) take  
6 affirmative action to abate the violation, and (ii) reinstate the complainant to his or  
7 her former position together with compensation (including back pay), terms,  
8 conditions, and privileges of his or her employment. The Secretary may order  
9 such person to provide compensatory damages to the complainant. If an order is  
10 issued under this subparagraph, the Secretary, at the request of the complainant,  
11 shall assess the person against whom the order is issued a sum equal to the  
12 aggregate amount of all costs and expenses (including attorneys' and expert  
13 witness fees) reasonably incurred (as determined by the Secretary), by the  
14 complainant for or in connection with, the bringing of the complaint upon which  
15 the order was issued.

16 (3)(A) The Secretary shall dismiss a complaint filed under paragraph (1) of  
17 this subsection, and shall not conduct the investigation required under paragraph  
18 (2) of this subsection, unless the complainant has made a prima facie showing  
19 that any behavior described in paragraphs (1) through (6) of subsection (a) of this

1 section was a contributing factor in the unfavorable personnel action alleged in  
2 the complaint.

3 (B) Notwithstanding a finding by the Secretary that the complainant has  
4 made the showing required by subparagraph (A) of this paragraph, no  
5 investigation required under paragraph (2) of this subsection shall be conducted  
6 if the manufacturer demonstrates by clear and convincing evidence that it would  
7 have taken the same unfavorable personnel action in the absence of such  
8 behavior. Relief may not be ordered under paragraph (1) of this subsection if the  
9 manufacturer demonstrates by clear and convincing evidence that it would have  
10 taken the same unfavorable personnel action in the absence of such behavior.

11 (C) The Secretary may determine that a violation of subsection (a) of this  
12 section has occurred only if the complainant has demonstrated that any behavior  
13 described in paragraphs (1) through (6) of subsection (a) of this section was a  
14 contributing factor in unfavorable personnel action alleged in the complaint.

15 (c) JUDICIAL REVIEW.— (1) Any person adversely affected or aggrieved  
16 by an order issued under subsection (a) of this section may obtain review of the  
17 order in the United States court of appeals for the circuit in which the violation,  
18 with respect to which the order was issued, allegedly occurred. The petition for  
19 review must be filed within 60 days from the issuance of the Secretary's order.  
20 Judicial review shall be available as provided in chapter 7 of title 5, United States

1 Code. The commencement of proceedings under this subsection shall not,  
2 unless ordered by the court, operate as a stay of the Secretary's order.

3 (2) An order of the Secretary with respect to which review could have been  
4 obtained under paragraph (1) of this subsection shall not be subject to judicial  
5 review in any criminal or civil proceeding.

6 (d) NONCOMPLIANCE.— Whenever a person has failed to comply with an  
7 order issued under subsection (b)(2) of this section, the Secretary may file a civil  
8 action in the United States district court for the district in which the violation  
9 occurred to enforce such order. In actions brought under this subsection, the  
10 district courts shall have jurisdiction to grant all appropriate relief, including  
11 injunctive relief and compensatory and exemplary damages.

12 (e) ACTION TO ENSURE COMPLIANCE.— (1) Any person on whose  
13 behalf an order was issued under subsection (b)(2) of this section may  
14 commence a civil action to require compliance with such order against the person  
15 to whom such order was issued. The appropriate United States district court  
16 shall have jurisdiction to enforce such order, without regard to the amount in  
17 controversy or the citizenship of the parties.

18 (2) The court, in issuing any final order under this subsection, may award  
19 costs of litigation (including reasonable attorneys' and expert witness fees) to any  
20 party whenever the court determines such award is appropriate.

1 (f) ENFORCEMENT.-- Any non-discretionary duty imposed by this section  
2 shall be enforceable in a mandamus proceeding brought under section 1361 of  
3 title 28, United States Code.

4 (g) APPLICABILITY TO CERTAIN EMPLOYEES.-- Subsection (a) of this  
5 section shall not apply with respect to any employee who, acting without direction  
6 from the manufacturer (or the agent of the manufacturer) deliberately causes a  
7 violation of any requirement of this Act, the Federal Food, Drug, and Cosmetic  
8 Act (21 U.S.C. 321 et seq.), or any other law or regulation relating to tobacco  
9 products.

10 (h) EFFECT ON OTHER LAWS.-- This section shall not be construed to  
11 expand, diminish, or otherwise affect any right otherwise available to an  
12 employee under Federal or State law to redress the employee's discharge or  
13 other discriminatory action taken by a manufacturer against the employee.

14 (i) POSTING.-- The provisions of this section shall be prominently posted in  
15 any place of employment to which this section applies.

**TITLE V — NATIONAL STANDARDS REDUCING EXPOSURE TO  
ENVIRONMENTAL TOBACCO SMOKE**

**SEC. 501. SMOKE-FREE ENVIRONMENTS.**

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following new title:

**"TITLE XXVIII — THE SMOKE-FREE ENVIRONMENTS ACT**

**"SEC. 2801. SMOKE-FREE ENVIRONMENT POLICY.**

**"(a) POLICY REQUIRED.** — In order to protect children and adults from cancer, respiratory disease, heart disease, and other adverse health effects from breathing environmental tobacco smoke, the responsible entity for each public facility shall adopt and implement at such facility a smoke-free environment policy which meets the requirements of subsection (b).

**"(b) ELEMENTS OF POLICY.** — Each smoke-free environment policy for a public facility shall —

(1) prohibit the smoking of cigarettes, cigars, and pipes, and any other combustion of tobacco, within the facility and on facility property within the immediate vicinity of the entrance to the facility;  
and

1                   "(2) require the posting of a clear and prominent notice of the  
2                   smoking prohibition in appropriate and visible locations at the public  
3                   facility.

4   The smoke-free environment policy may provide an exception to the prohibition  
5   specified in paragraph (1) for one or more specially designated smoking areas  
6   within a public facility if such area or areas meet the requirements of subsection  
7   (c).

8                   "(c) SPECIALLY DESIGNATED SMOKING AREAS. — A specially  
9   designated smoking area meets the requirements of this subsection if —

10                   "(1) the area is a negative pressure facility, and is ventilated in  
11                   accordance with specifications promulgated by the Administrator that  
12                   insure that air from the area is directly exhausted to the outside and does  
13                   not recirculate or drift to other areas within the public facility;

14                   "(2) nonsmoking individuals are not required to enter the area for any  
15                   purpose; and

16                   "(3) cleaning and maintenance functions are performed only when no  
17                   smoking is occurring.

18   "SEC. 2802. CITIZEN ACTIONS.

1       "(a) IN GENERAL. — An action may be brought to enforce the  
2 requirements of this title by any aggrieved person, any State or local government  
3 agency, or the Administrator.

4       "(b) VENUE. — An action to enforce this title may be brought in any United  
5 States district court for the district in which the defendant resides or is doing  
6 business to enjoin any violation of this title or to impose a civil penalty for any  
7 such violation in the amount of not more than \$5,000 per day of violation. The  
8 district courts shall have jurisdiction, without regard to the amount in controversy  
9 or the citizenship of the parties, to enforce this title and to impose civil penalties  
10 under this title.

11       "(c) NOTICE. — An aggrieved person shall give any alleged violator notice  
12 of at least 60 days before commencing an action under this section. No action  
13 may be commenced by an aggrieved person under this section if the alleged  
14 violator complies with the requirements of this title within such 60-day period and  
15 thereafter.

16       "(d) COSTS. — In issuing a final order in any action brought pursuant to  
17 this section, the court may award costs of litigation (including reasonable attorney  
18 and expert witness fees) to any prevailing plaintiff, whenever the court determines  
19 such award is appropriate.

1       "(e) PENALTIES. — The court in any action under this section shall have  
2       discretion to order that civil penalties be used for projects which further the  
3       policies of this title. The court shall obtain the view of the Administrator in  
4       exercising such discretion and selecting any such projects.

5       "SEC. 2803. NON-PREEMPTION.

6       "Nothing in this title shall preempt or otherwise affect any other Federal,  
7       State or local law which provides protection from health hazards from  
8       environmental tobacco smoke that is at least as stringent as the requirements of  
9       this title or otherwise further restricts or eliminates employee and public exposure  
10      to smoking in workplaces and in other public and private places, facilities and  
11      areas. Nothing in this title shall preempt or otherwise affect any Federal rule or  
12      regulation that restricts or eliminates smoking in any Federal building or other  
13      facility.

14      "SEC. 2804. REGULATIONS.

15      "The Administrator shall promulgate such regulations as the Administrator  
16      determines to be necessary to carry out this title. Funds required to enforce the  
17      provisions of this title shall be derived from payments by tobacco product  
18      manufacturers under TITLE VIII OF THE TOBACCO PRODUCTS CONTROL  
19      ACT OF 1998.

1 "SEC. 2805. DEFINITIONS.

2 "As used in this title —

3 "(1) The term 'Administrator' means the Administrator of the  
4 Occupational Safety and Health Administration.

5 "(2) The term 'public facility' means any building regularly entered by  
6 10 or more individuals at least one day per week, including any such  
7 building owned by or leased to a Federal, State, or local government entity.  
8 Such term shall not include any building or portion thereof regularly used  
9 for residential purposes, restaurant (other than a fast food restaurant), bar  
10 (including a bar in a hotel), private club, guest room in a hotel, casino,  
11 bingo parlor, tobacco merchant, or prison. As used in this paragraph, the  
12 term 'fast food restaurant' means any restaurant or chain of restaurants  
13 which primarily distributes food by means of a customer pick-up, either at a  
14 counter or at a drive-through window.

15 "(3) The term 'responsible entity' means, with respect to any public  
16 facility, the owner of such facility, except that in the case of any such facility  
17 or portion thereof which is leased, such term means the lessee.

18 The Administrator may promulgate regulations clarifying the definitions set forth  
19 in paragraph (2) of this section if the Administrator determines that a clarification  
20 is necessary to ensure that facilities frequented primarily by individuals under the

1 age of 18 years are included within such definition. In promulgating any such  
2 regulation, the Administrator may consider such factors as whether a facility  
3 either has attached playgrounds or play areas for children, utilizes advertising  
4 that features or prominently includes cartoon characters or free distribution of  
5 toys, advertises services or meals with portions or characterizations that  
6 emphasize that they are designed primarily to be consumed by individuals under  
7 the age of 18 years, or such other factors as the Administrator considers  
8 appropriate.

9 "SEC. 2806. EFFECTIVE DATE.

10 "The requirements of this title shall take effect one year after the date of  
11 enactment of this title, without regard to whether the regulations required by  
12 section 2804 have been promulgated."

**TITLE VI — APPLICATION TO INDIAN TRIBES**

**SUBTITLE A — APPLICATION OF ACT TO INDIAN TRIBES**

**SEC. 601. APPLICATION OF ACT.**

(a) INDIAN LANDS.— The provisions of this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.), and regulations of the Food and Drug Administration relating to the manufacture, distribution and sale of tobacco products shall apply on Indian lands, 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.

(b) RELIGIOUS PURPOSES.— Nothing in this Act shall be construed to prohibit the manufacture, possession or use of tobacco or tobacco products by an Indian tribe or member of a tribe for religious purposes.

**SEC. 602. TAXATION.**

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 Indian lands, to the same extent such tax or fee applies to any other person under law.

**SEC. 603. TRIBAL PROGRAMS AND AUTHORITY.**

1 (a) TREATMENT. —For purposes of this Act, the Food and Drug  
2 Administration may (in accordance with subsection (b) of this section), treat any  
3 Federally-recognized Indian tribe as a State, and provide grant and contract  
4 assistance to such tribe in order to carry out the provisions of this section.

5 (b) LIMITATION. —Such treatment of an Indian tribe as a State shall only  
6 be authorized if —

7 (1) the Indian tribe has a governing body carrying out substantial  
8 governmental powers and duties;

9 (2) the functions to be exercised by the Indian tribe under this section  
10 pertain to activities on Indian lands subject to this Act; and

11 (3) the Indian tribe is reasonably expected to be capable of carrying  
12 out the functions required under this Act.

13 **SEC. 604. LICENSING.**

14 Regulations of the Food and Drug Administration which establish a retail  
15 licensing program for the sale of tobacco products shall apply on Indian lands,  
16 and the program of each tribe shall be no less strict than the program of the State  
17 in which the tribe is located. If the Food and Drug Administration determines that  
18 an Indian tribe does not qualify for treatment as a State, the Food and Drug  
19 Administration shall either administer directly such retail licensing program or

1 delegate such authority to the State to be exercised in conjunction with such  
2 State's program.

3 **SUBTITLE B — TOBACCO COMPENSATION**

4 **AND PUBLIC HEALTH GRANTS**

5 **SEC. 611. SETTLEMENT FUND PAYMENTS.**

6 (a) DISTRIBUTION OF FUNDS.-- A portion of the settlement funds to  
7 which a State is otherwise entitled shall be paid to the Secretary for distribution to  
8 the Indian tribes which have been certified under this title by the Food and Drug  
9 Administration for treatment as States. The portion of funds to be paid on behalf  
10 of Indian tribes shall be determined by the proportion of enrolled tribal members  
11 resident on the reservation to the total population of the State in which the tribe is  
12 located. Funds distributed to Indian tribes shall be used for the same purpose as  
13 such funds are to be used by the States and shall be subject to the same  
14 compliance requirements for retail sales to individuals under the age of 18 years  
15 as apply to the States under this Act.

16 (b) ANNUAL PAYMENT. —(1) The Secretary shall pay annually to the  
17 governing body of each Indian tribe its share of the funds for its use under a plan  
18 approved by the Food and Drug Administration. Such plan shall provide for  
19 annual certification by the Food and Drug Administration that the Indian tribe is in

1 compliance with the requirements of the Federal Food, Drug, and Cosmetic Act  
2 (21 U.S.C. 321 et seq.), this Act, and any applicable regulations pursuant to such  
3 Acts. Such certification shall be carried out under the same standards as apply to  
4 the States.

5 (2) If the Secretary does not distribute to an Indian tribe all or any portion of  
6 the funds in any given year because the tribe has not been certified under this  
7 subsection or has not met the compliance requirements for retail sales to  
8 individuals under the age of 18 years under the amendments made by this Act,  
9 such funds shall be distributed to other qualified tribes in the same State for the  
10 same purposes and on the same proportional basis, less the population of the  
11 non-qualified tribe, as other settlement funds are distributed to the tribes.

## 12 **SUBTITLE C — OBLIGATIONS OF TOBACCO**

### 13 **PRODUCT MANUFACTURERS**

#### 14 **SEC. 621. LIMITATIONS ON ACTIVITIES.**

15 (a) **PROHIBITED ACTIVITIES.** — No tobacco product manufacturer shall  
16 engage in any activity on Indian lands subject to this Act in which it may not  
17 otherwise engage within a State.

18 (b) **SALE TO TRIBE.** — A tobacco product manufacturer shall not sell  
19 tobacco products for manufacture, distribution, or sale to an Indian tribe, or to a

- 1 manufacturer, distributor, or retail seller subject to the jurisdiction of an Indian
- 2 tribe, except under the same terms and conditions as are imposed by such
- 3 manufacturer upon other manufacturers, distributors and retail sellers under this
- 4 Act or any applicable regulations.

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**TITLE VII -- CIVIL LIABILITY**

**(Reserved)**

**TITLE VIII -- FUNDING**

**(Reserved)**

**TITLE IX -- DOCUMENT DISCLOSURE**

**(Reserved)**

**TITLE X -- MISCELLANEOUS PROVISIONS**

**SEC. 1001. SEVERABILITY.**

If any provision of this Act or an amendment made by this Act is held unconstitutional, or the application of such provision or amendment to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such Act and amendments to any other person or circumstance shall not be affected thereby.

**DRAFT**

Discussion Draft - September 23, 1997

**ARTICLES OF INCORPORATION****OF**  

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The undersigned incorporator[s], desiring to form a corporation (the "Corporation") pursuant to the provisions of the Indiana Nonprofit Corporation Act of 1991 (the "Act"), execute[s] the following Articles of Incorporation:

**ARTICLE I****Name**

The name of the Corporation is \_\_\_\_\_.

**ARTICLE II****Classification of Corporation**

The Corporation is a public benefit corporation.

**ARTICLE III****Purposes and Powers**

Section 3.1. Purposes. The purposes for which the Corporation is formed are to operate exclusively for charitable, educational, and scientific purposes within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, or any subsequent Federal tax law. In furtherance of these purposes, the Corporation may:

- (a) engage in activities designed to reduce smoking amongst the minority and women communities;
- (b) develop educational and marketing materials directed to the minority and women communities to counter the efforts of smoke promotions targeted at such communities;
- (c) conduct research designed to examine the efforts of smoking in the minority and women communities and ways of reducing the rates of smoking in such communities;
- (d) raise, invest, and expend funds exclusive for the benefit of, to perform the functions of and to carry out the purposes of a specified class of qualified nonprofit corporations exempt from federal taxation pursuant to Section 501(a) and who are classified as organizations described in section 509(a)(1) or (2) of the Internal Revenue Code of 1986, or any subsequent Federal tax law,