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AMERICAN CANCER SOCIETY

POSITION ON THE PROPOSED

TOBACCO SETTLEMENT

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AMERICAN CANCER SOCIETY**INTRODUCTION**

The American Cancer Society (ACS) believes that the settlement process between 40 Attorneys General and the tobacco industry provides a rare opportunity to make substantial inroads in combating tobacco related illnesses -- the largest cause of death and disease in the United States. More importantly, the proposal has the potential to reverse the frightening increase in teenage tobacco use.

Perhaps because the settlement proposal was adopted without the benefit of significant public scrutiny or debate, it is clear that as currently presented, the settlement is flawed. It includes, in our view, obvious shortcomings that must be addressed by Congress to effectuate important tobacco control policies. We believe that, using the proposed settlement as a platform, Congress can craft balanced legislation that resolves most litigation and ensures adequate public health protection from the devastating effects of tobacco use.

The proposed settlement must be viewed in the context of the devastating effects of tobacco use on health and the continued attempts at the federal, state and local levels to address this important public health problem. Our nation took an important step toward mitigating the harm of tobacco use through the adoption of advertising restrictions and warning labels in the 1960s. Since that time, states have taken the lead in tobacco control through imposing excise taxes on cigarettes and tobacco products, banning billboards, requiring ingredient disclosure, and through policies aimed at protecting non-smokers from the secondary effects of smoking in public places and controlling underage access to tobacco products. The settlement proposal offers the opportunity to build upon these state and local efforts to establish a national policy for tobacco control with a primary goal of protecting our children from ever starting to smoke. ~~However, no single piece of Federal legislation can represent a permanent, long-term approach to the problem of tobacco use.~~ The American Cancer Society will continue to work for adoption of even stronger tobacco control policies by Congress, state legislatures, local governments, and public health officials.

Despite state and local efforts to control underage use of tobacco, the U.S. has witnessed a disturbing increase in the rate of teenage tobacco use. Over 3,000 teenagers become hooked on tobacco for the first time every day. Although the tobacco industry has consistently denied that it attempts to encourage teenage tobacco use, empirical evidence suggests that advertising in youth-oriented publications, use of cartoon characters in advertising, and the steady display of young, healthy models in tobacco advertising all have the effect of increasing rates of teenage tobacco use. The settlement proposal represents an opportunity for Congress to enact legislation to address the problem of underage tobacco use

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through advertising restrictions, education efforts, and industry incentives to decrease the rate of tobacco use among minors.

One of the most pernicious aspects of tobacco products is the addictive effect of nicotine. The scientific community unanimously agrees that nicotine has powerful addictive properties. Indeed, we now know that the tobacco industry has been fully aware of these properties for decades. Reducing or even eliminating nicotine from tobacco is critical to any effective tobacco control policy. The proposed settlement attempts to address this issue through the regulation of tobacco product development and manufacturing. Congressional action on control of nicotine should expand the authority of FDA to regulate the sale, manufacture and marketing for all tobacco products including cigars and pipe tobacco.

The American Cancer Society believes that any evaluation of the settlement proposal must consider the following questions: Is the FDA given appropriate tools to effectuate critical public health goals through regulation of tobacco products? Are regulators, and the public, given appropriate access to industry information on the health effects of tobacco? Are the roles of state and local governments in implementing tobacco control policies properly enhanced and preserved? Does the proposal include sufficient incentives for the reduction of tobacco consumption and the development of less hazardous products?

These recommendations are, to a large extent, based upon the Analysis and Review of the Tobacco Settlement that was also drafted and disseminated by the ACS. Based on the work of experts in law, economics, medical ethics and public health, the Analysis and Review includes separate sections on: a summary of the current FDA rule; a special legal analysis of the United States District Court case upholding, in part, the FDA rule; a special legal analysis of the proposed authority for the FDA to regulate nicotine content of tobacco products; an economic analysis of the rule; and a discussion of important constitutional issues raised by the settlement. In addition, we provide important factual information about public health and tobacco. Specific information in these documents supplements our recommendations.

The following document outlines our recommendations for the Congressional response to the settlement proposal. Most, but not all, provisions are analyzed. We have placed the most emphasis on seven principal provisions which we believe are the most important to public health. Our review includes a summary of the various provisions, an analysis of them, and recommended changes to legislation that would implement the proposed settlement. We invite critical comment and analysis of our findings and recommendations and look forward to working with our colleagues in efforts to develop what could become the most important public health legislation enacted in this century.

AMERICAN CANCER SOCIETY**ANALYSIS OF PRINCIPAL TERMS OF
THE PROPOSED TOBACCO SETTLEMENT****I. INDUSTRY PAYMENTS**

- **Summary of Settlement Provisions (pp. 34-35)**

The settlement requires the tobacco industry to make total payments of \$368.5 billion (in unadjusted dollars) over 25 years. This amount includes a lump sum payment of \$10 billion due immediately upon the signing of the statute, followed by annual base payments ranging between \$8.5 billion and \$15 billion. The amount of each year's scheduled base payment will be increased over the previous year's payment by the greater of 3% or the Consumer Price Index ("CPI"). In addition, the payments shall be adjusted according to changes in the domestic volume of tobacco product sales. Any decrease in the scheduled annual payment, however, will be offset by a surcharge of 25% of any increase in the industry's profits from domestic sales compared to its "base year" profits.

In order to maximize the reduction in youth tobacco use, the settlement requires tobacco manufacturers to pass on the costs of these payments to tobacco consumers by increasing product prices. The settlement will permit tobacco companies to deduct these expenses from their federal income tax liabilities as ordinary and necessary business expenses.

- **ACS Analysis**

From a public health perspective, the substantial industry payments are highly desirable as a means of funding public health programs. In addition, the requirement that tobacco companies pass along the payments to consumers in higher prices will likely reduce tobacco consumption almost immediately, especially among minors. The proposal, however, has several serious shortcomings that must be addressed.

First, the amount of the required industry payments may be too small to produce significant reductions in youth tobacco use. In his recent economic analysis of the settlement, Professor Jeffrey E. Harris, M.D., Ph.D. of the Massachusetts Institute of Technology and Massachusetts General Hospital concludes that the present discounted value of the required \$368.5 billion payments is actually only \$194.5 billion. ^{1/} As a result, Dr. Harris argues that the payments

^{1/} Harris, J.E., Economic Analysis of the Proposed Settlement, American Cancer Society Analysis and Review of the Tobacco Settlement, July 24, 1997. This analysis is at Tab 16 of the ACS Analysis and Review.

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would produce a 41-cent per pack increase in the price of cigarettes in Year One. This price increase would gradually grow to 62 cents per pack (in 1996 dollars) by Year Five and would remain at that level indefinitely.

Secondly, the tax treatment of settlement costs will further reduce the economic impact upon the tobacco industry and will have a negative impact upon federal income tax revenues. Because the required payments are tax deductible to the tobacco companies, the payments will reduce the industry's federal income tax liability and will reduce the governments revenue receipts. Thus, much of the burden of the required payments would be transferred from the tobacco industry to the federal government, partially transforming the settlement into a federally funded program.

There is widespread agreement among health economists and policy analysts that almost no other public health strategy would exhibit the speed and cost-effectiveness of impact achieved by increasing the price of tobacco products. Increases in price will decrease both participation (the number of smokers) and daily consumption amounts (the number of cigarettes per person per day). Economists have estimated that a 10% increase in the price of cigarettes will reduce overall smoking among adults by about 4% and will reduce smoking initiation by about 6.75% among minors (this does not include decreases in consumption among minors).

Many public health advocates, including the Koop/Kessler commission have argued that an even larger price increase, as much as \$2 per pack, is desirable to reduce tobacco consumption as much as possible while still remaining economically feasible. In previous research, Dr. Harris concluded that the tobacco industry could sustain price increases of more than \$2 per pack and that it could afford to make damage payments sufficient to produce such price increases. By producing only a 62-cent price increase, the settlement falls far short of the possible reduction in youth tobacco use that can be attained by a greater increase in price.

- **Recommended Change**

Congress must design a payment scheme that will raise the price of tobacco products by requiring additional payments to be made by the industry and/or consumers of tobacco. This will have the effect of collecting additional money for compensation and for public health programs and will fulfill the more important goal of decreasing the youth tobacco consumption rate as much as possible. We strongly recommend that, as part of legislation implementing the proposed settlement, the cigarette excise tax should be raised by at least \$2.00, with proportionate increases in the tax on cigars and pipe tobacco.

AMERICAN CANCER SOCIETY**II. FDA REGULATION OF NICOTINE AND OTHER TOBACCO CONSTITUENTS****• Summary of Settlement Provisions (pp. 15-18)**

For *twelve years*, the FDA is permitted to adopt performance standards that require the modification of existing tobacco products, including a gradual reduction (but not the elimination) of nicotine and the possible elimination of other harmful components of tobacco products. These modifications may be required based on a finding that such changes:

- (a) will significantly reduce health risks;
- (b) are technologically feasible, and
- (c) will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard.

The authority to require any product modification during this initial twelve-year period must be based on a showing of "substantial evidence" that is documented in an administrative record and developed through a formal rulemaking process, including a hearing. Manufacturers of tobacco products that would be affected by any proposed modification have a right of judicial review. Congress also may intervene if it so chooses.

After the initial twelve year period, the FDA is permitted to set product safety standards that go beyond the standards it is authorized to set during the first twelve years. Specifically, the FDA is permitted to require the alteration of tobacco products, including the elimination of nicotine or other harmful components of tobacco products based on a finding that:

- (a) the safety standard will result in a significant overall reduction of the health risks to tobacco consumers as a group,
- (b) the modification is technologically feasible, and
- (c) the modification will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard.

According to the agreement, given the significance of such an action, the FDA may require the elimination of nicotine based on a "preponderance of the evidence" pursuant to, at a manufacturer's election, a hearing or notice and comment rulemaking with a right of judicial review. Furthermore, any such action must be phased in, and the phase-in period may not begin for two years in order to permit Congressional review.

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Importantly, in any judicial review of the FDA's action, deference to the FDA's findings will depend on the extent to which the matter at issue is within the agency's field of expertise.

- **ACS Analysis**

The 1996 FDA rule asserted the agency's jurisdiction over cigarettes under the current medical device law. A federal district court affirmed this assertion of authority in the Coyne Beahm case. Because the FDA rule does not seek to control the development or manufacturing of tobacco products or impose limitations on the nicotine content of these products, the district court decision did not address the specific question of whether FDA can impose these restrictions.

The ACS believes that the procedural hurdles imposed by this section are wholly unjustified from a legal or public health perspective. Requiring the FDA to engage in "formal rule making" before it can adopt performance standards to modify tobacco products (including reduction of nicotine) may enable a single tobacco company to complicate and encumber the administrative process for years in order to delay a rule from going into effect. Additionally, the burden on the agency to demonstrate that it meets specified statutory findings by a "preponderance of the evidence" before it may ban nicotine altogether introduces a new, and presumably higher, standard into administrative law proceedings. Finally, it would be difficult for FDA to demonstrate the negative finding that "significant demand for contraband products" will not result from changes to current tobacco products. This requirement could be interpreted to prevent the FDA from acting even if the benefits of the rule far exceeded the costs of black market sales in high nicotine cigarettes.

- **Recommended Changes**

1. *Specifically authorize FDA, after notice and opportunity for comment under 5 U.S.C. § 553, to develop performance standards for tobacco products designed to reduce or eliminate any constituent, including nicotine.*
2. *Delete the provision governing FDA activities after 12 years and apply a single standard that would apply from the effective date of the Act forward as follows.*
3. *Eliminate the proposed heightened standards of proof ("substantial evidence" and "preponderance of the evidence") required for agency action and allow traditional administrative law to apply.*

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4. *Delete requirements that FDA demonstrate that any modification in tobacco products must be based on a finding that the modification will not result in significant contraband.*
5. *Federal requirements to reduce nicotine must apply to cigars and pipe tobacco, as well as cigarettes.*

III. PUBLIC DISCLOSURE OF PAST AND FUTURE INDUSTRY DOCUMENTS

- **Summary of Settlement Provisions (Appendix VIII, p. 64)**

The settlement requires manufacturers to establish and maintain a centralized depository for documents "produced" in pending litigation. The documents will be available to Congress, state and federal agencies, and the public under certain conditions. The industry is permitted, however, to withhold any documents it considers to be "privileged" and any materials it considers to represent trade secrets. Materials regarding research on health, safety and less hazardous products also will be included, with the exception of legitimate trade secrets.

Upon settling the AG suits, the companies are permitted to re-review all documents claimed as privileged and create a new inventory of privileged documents. Anyone wishing to challenge the industry's assertion of privilege or trade secret must file a claim, which will be decided by a three-judge panel.

- **ACS Analysis**

It is clear that the tobacco industry has not disclosed all it knows about the dangers and addictive properties of tobacco products. During a period when millions of Americans contracted lung cancer or other tobacco-induced diseases, the industry did not release its own internal research regarding the harmful effects of tobacco use. Thus, complete disclosure of industry research regarding the effects of tobacco use is essential to a national tobacco control policy.

The settlement proposal provides no explicit deadline for the production of the limited number of documents the industry has already agreed to produce. More importantly, the settlement does not compel tobacco manufacturers to turn over hundreds of thousands of documents, representing millions of pages, currently protected by attorney-client privilege. Many of these documents might have come to light through litigation. The documents are believed to contain incriminating evidence on marketing research, strategies to induce teenagers to use tobacco products, studies on the health dangers of tobacco, and political strategies.

Although the settlement proposal includes a mechanism for resolving disputes over privileged documents, this process is overly cumbersome and

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extremely time-consuming. Companies could potentially stall review of any challenged material through the three-judge panel by insisting on a line-by-line review of the documents. Thus, what is potentially the most critical information may not reach the public for years, if ever.

The ACS believes that all information on the harmful effects of smoking -- whether or not it is privileged or trade secret information -- should be provided to FDA for use in development of Product Standards and reduced risk products. The FDA has strict requirements relating to non-disclosure of trade secrets and has vast experience in regulating products on the basis of confidential information to review documents that are currently protected under attorney-client privilege or are trade secrets.

A • **Recommended Changes**

1. Congress should ensure that both state and federal courts have jurisdiction to quickly resolve privilege claims. The burden should be on industry to demonstrate why documents should not be disclosed.
2. Federal legislation regarding disclosure of industry documents should also explicitly require the industry to release to the FDA all information -- including research and marketing data -- that is relevant to public health, safety, and the development of less hazardous tobacco products.

IV. SCOPE AND EFFECT / PREEMPTION

- **Summary of Settlement Provisions (pp. 32-33; 26-27)**

The settlement preserves state and local authority to:

- (a) restrict or eliminate underage access to and consumption of tobacco;
- (b) further restrict or eliminate ETS exposure in the workplace and "other public and private places and facilities;" and
- (c) restrict or eliminate the sale or distribution of tobacco products.

The terms of the settlement document "preserve" current federal law providing for national uniformity of warning labels, packaging and labeling requirements and advertising and promotion requirements related to tobacco and health. In addition, the preemption provisions of section 521 of the Food, Drug, and Cosmetic Act (FDC Act), designed to provide uniform regulation of medical devices, would apply to tobacco products since they will be regulated as devices.

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However, under the "Penalties and Enforcement" provisions of the settlement proposal, state enforcement actions may not impose obligations beyond those imposed by the Act (except where the Act does not specifically preempt additional state law obligations) and is limited to the penalties listed. Thus, it appears that the settlement would preempt state and local laws with respect to penalties and enforcement.

- **ACS Analysis**

The Federal Cigarette Labeling and Advertising Act (the "Labeling Act") requires cigarette manufacturers to include specified warning labels on cigarette packages, and it bans cigarette advertising on television, radio, and other media subject to the jurisdiction of the Federal Communications Commission. The Labeling Act also contains a provision preempting state and local laws to the extent that they impose: (1) a requirement or prohibition, (2) based on tobacco use and health, (3) with respect to advertising or promotion. (See Cipollone v. Liggett Group, Inc.). All three of these criteria must be met in order for the state or local law to be preempted.

Although the Labeling Act's preemptive force has been construed narrowly by the United States Supreme Court, many state and local regulations fall under its scope. For example, any state or local regulation which restricts tobacco advertising or promotions with the goal of protecting health is preempted. In addition, many common law tort claims are preempted. For example, if a plaintiff claims that post-1969 advertising or promotions should have included additional, or more clearly stated warnings or information, these claims are preempted by the Labeling Act.

Similarly, in Medtronic, Inc. v. Lohr, the court narrowly construed the preemption provisions of the FDC Act, which preempts requirements that are "different from, or in addition to any requirement applicable under this Act to the device" and which relate to safety or effectiveness of the device or other matter included in such requirement. Noting that throughout our history, the states have exercised their police powers to protect the health and safety of their citizens "because these are 'primarily and historically... matter[s] of local concern'" the court held that the provision does not preempt state common law negligence actions. The court appears to hold that only if FDA promulgates a requirement, and a state imposes a specific duty on a device manufacturer that is "different from, or in addition to" the FDA requirement, does preemption take place.

- **Recommended Changes**

As noted in the introduction, state and local governments have undertaken significant efforts to control underage use of tobacco, through imposing excise taxes, restrictions on sales to minors, labeling and disclosure requirement and

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policies protecting citizens from secondary effects of smoking. ACS believes that as a general rule, states and localities should be authorized to enact laws that are the same as, or more stringent than, federal tobacco control laws. The following changes would implement this policy:

- 1. The "Penalties and Enforcement" provision would preempt state laws governing penalties and enforcement. These provisions appear to contradict provisions found elsewhere in the proposed settlement. Legislation should provide that state and local enforcement authority and penalties may be more stringent than federal law.*
- 2. In addition, the ACS recommends that Congress carefully review the implications of any new federal law regulating tobacco products as medical devices and clearly specify instances, such as requirements for modification of tobacco products or good manufacturing practice requirements, in which preemption is warranted. Requirements under the Federal Food, Drug and Cosmetic Act for labeling and advertising of devices should not serve as barriers to additional state and local requirements as long as they do not conflict with requirements imposed by the FDA.*
- 3. Because the Labeling Act precludes many state and local health requirements implementing the initiatives as well as many common law tort claims, the ACS recommends that the legislation include a provision amending the preemptive language of the Labeling Act. Such an amendment should permit states and localities to enact laws which enhance and supplement the goals of the Labeling Act.*

V. REDUCING UNDERAGE TOBACCO CONSUMPTION AND "LOOK BACK" PROVISIONS

- **Summary of Settlement Provisions (pp. 24-25)**

The "look-back" provision sets specific targets for the reduction of underage smoking and use of smokeless products over the next ten years. These targets are as follows:

Smoking Reduction	Smokeless Reduction	Year
30%	25%	5th
50%	35%	7th
60%	45%	10th

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If the targets are not met, the FDA may impose a mandatory surcharge on the relevant industry (i.e., cigarette or smokeless tobacco) based on the estimated profit the industry would earn over the lives of all underage users in excess of the target. The surcharge is subject to an annual cap of \$2 billion for the cigarette industry and a proportional cap for the smokeless tobacco industry.

Manufacturers are eligible to receive a partial abatement, up to 75%, of the surcharge. To receive the refund, a company must prove:

- (a) it "acted in good faith" and in full compliance with all laws;
- (b) it pursued "all reasonably available measures" to attain the targets; and
- (c) there is no evidence it took action to undermine achievement of the goals.

Additionally, states are required to have a "no sales to minors" law. Each state must conduct 250 random, unannounced inspections per one million population annually to ensure retailer compliance. The FDA must determine, on an annual basis, whether each state has "pursued all reasonably available measures" to enforce the ban on tobacco sales to minors. Further, FDA must presume that a state has not met this standard if the following compliance rate targets are not met:

Year	Retail Compliance Rate
5th	75%
7th	85%
10th	90%

States that fail to meet enforcement targets will lose Medicaid-related funds from the settlement for each percentage point it exceeds a target, up to a maximum of 20%. The FDA must refund up to 75% of the withheld funds, however, if the state shows:

- (a) it acted in good faith and full compliance with all laws;
- (b) it pursued "all reasonably available measures to attain" the targets; and
- (c) there is no evidence it took action to undermine the achievement of the goals.

• ACS Analysis and Recommended Changes

While the *concept* is sound, the effect of the "look back" provisions may be limited. As written, the proposal does not include sufficient economic incentive to ensure that industry will meet the targets established in the proposed settlement. However, properly crafted, "look back" provisions can provide a strong motivation for the industry to comply with other aspects of the settlement and to

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take seriously their responsibility and role in decreasing underage tobacco consumption. As they are included in the settlement proposal, however, the provisions are seriously flawed and should be amended. Proposed changes include the following:

1. Lower targets should not be allowed for smokeless tobacco products than for cigarettes or other tobacco products. Over the past 10 years, the increase in use of smokeless products among teenage boys has outpaced that of cigarettes.

Recommended Change: Raise the targets for smokeless tobacco products to the same level as cigarettes. Any legislation should include all tobacco products; i.e. cigars, pipe tobacco as a target objective.

2. There is insufficient incentive for an individual manufacturer to curb its own marketing efforts to attract potential underage users, since it will not be proportionally accountable for any violation of the targets.

Recommended Changes

- a. Remove the perverse incentive for tobacco companies to gain a disproportionate share of the underage market by imposing the surcharge on each company individually based on brand-specific youth consumption.
 - b. Appropriate sales data, by brand, must be provided by the companies to allow evaluation of performance by individual companies.
3. An economic analysis of the tobacco industry by Jeffrey Harris, M.D., Ph.D., an economist at the Massachusetts Institute of Technology, indicates that the present value of the \$80 million surcharge and the \$2 billion cap are too low to serve as an effective deterrent. ^{2/} According to Dr. Harris, even under optimistic assumptions, the industry could pass along a \$2 billion surcharge to consumers by increasing prices only 8 to 10 cents per pack. The surcharge must be high enough to ensure vigorous efforts to meet statutory targets.

^{2/} See Tab 16 of the ACS Review and Analysis.

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Recommended Change: *The \$2 billion cap should be eliminated, and surcharge payments should be at a rate to provide an effective incentive for industry to help achieve results.*

4. The rebate provision is so broadly worded that it could be interpreted to allow a rebate even if a manufacturer took only token efforts to meet targets. Moreover, the reward so high (mandatory 75% refund) that the industry has a much stronger incentive to fight for the rebate than to achieve the youth reductions, thus completely undermining the intent and effectiveness of the "look-back" provisions.

Recommended Change: *Eliminate the rebate altogether.*

5. In an effort to minimize the effectiveness of random, unannounced inspections by local authorities, the tobacco industry has succeeded in passing laws in many localities banning the use of minors as straw purchasers.

Recommended Change: *Implementing legislation should explicitly authorize state and local governments to use minors in compliance checks.*

6. The Secretary of Health and Human Services has estimated that three-fourths of the approximately one million tobacco outlets sell tobacco to minors.

Recommended Change: *With this many outlets, it is critical that any "no sales to minors" law must require the licensing authority to conduct, or to arrange for, periodic compliance checks at every licensed store. These checks should be conducted, at a minimum, two or three times annually. 3/*

VI. DISCLOSURE AND REGULATION OF NON-TOBACCO INGREDIENTS

- **Summary of Settlement Provisions (pp. 19-20)**

Under the Comprehensive Smoking Education Act ("Smoking Education Act"), each manufacturer, packer or importer of cigarettes must annually

3/ See No Sale: Youth, Tobacco and Responsible Retailing: Developing Responsible Retail Sales Practices and Legislation to Reduce Illegal Tobacco Sales to Minors. Findings and Recommendations of a Working Group of State Attorneys General.

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provide the Secretary with a list of ingredients added to cigarettes during their manufacture. The list may not identify the company which uses the ingredients or the brand of cigarettes which contains them. The Secretary is to transmit to Congress a report based on such information of a summary of research activities and their findings, on the health effects of the ingredients, and information on any ingredient which, in the judgment of the Secretary poses a health risk to cigarette smokers.

The settlement proposes adoption of legislation that would supersede the reporting requirements of the Smoking Education Act and replace them as follows:

1. Manufacturers would be required to provide FDA on a confidential basis a list of non-tobacco ingredients, by brand.
2. Within 5 years of enactment of the legislation, manufacturers would be required to submit for each ingredient, a safety assessment demonstrating that "there is a reasonable certainty in the minds of competent scientists that the ingredient (up to a specified amount) is not harmful" under intended conditions of use. FDA must review the safety and approve or disapprove the use of the ingredient. If FDA takes no action within 90 days, the ingredient would be deemed approved.
3. New ingredients, or the addition of current ingredients beyond the specified amount, would be subject to comparable requirements to submit a safety assessment.
4. The settlement contemplates treatment of some ingredient information as confidential, and protects ingredient information not subject to disclosure under federal food law. For 5 years, such information would not be required to be disclosed unless FDA disproves the safety of an ingredient.

- **ACS Analysis**

Overall, the proposal for the first time would require submission of specific information on tobacco ingredients, by brand, to FDA and require a demonstration of safety of the ingredient, much like that required of a food additive.

The description of the confidentiality provisions is somewhat unclear, however, since as a general rule there is no trade secret provision under food law that protects disclosure of ingredients. Percentages of ingredients are protected, as are flavors and manufacturing processes. But the existence of an ingredient is not regarded as trade secret information.

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- **Recommended Changes**

- * 1. *"Ingredients" must include all additives and other substances derived from tobacco, as well as non-tobacco ingredients.*
- * 2. *There is no justification for denying the public access to information on the existence of ingredients in tobacco and legislation including such a provision should be rejected.*
- 3. *The legislation should specifically provide FDA with the authority and responsibility to establish safety standards to serve as the basis for the safety assessment.*
- 4. *The provision authorizing inclusion of an ingredient in tobacco if a safety assessment is not acted upon within 90 days should be deleted.*
- 5. *The legislation should make it clear that a safety assessment must include an evaluation of ingredients used in combination with each other, as well as the fact that ingredients are altered through burning.*

VII. REDUCED RISK PRODUCTS / "SAFER CIGARETTES"

- **Summary of Settlement Provisions (pp. 14-15)**

The proposed agreement would bar tobacco product manufacturers from making claims that state or imply a reduced health risk, unless it can demonstrate to the FDA that the product in fact "significantly reduces the risk to health" compared to ordinary tobacco products. Additionally, the FDA has authority to approve all health claims made in advertisements in order to "prevent the public from being misled."

With regard to tobacco products that the agreement refers to as "less hazardous," the FDA may permit scientifically-based health claims. In addition, the FDA can provide exceptions to the advertising restrictions that apply to other products if it determines that to do so would "reduce harm and promote the public health."

If a manufacturer develops or acquires technology that reduces the risk from tobacco products, it is required to notify FDA and cross license such technology for a reasonable fee to other manufacturers. Procedures to resolve license fee disputes and assurance of protection of confidential data during the development process are contemplated.

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Importantly, in any judicial review of the FDA's action, deference to the FDA's findings will depend on the extent to which the matter at issue is within the agency's field of expertise.

- **ACS Analysis**

Mandatory licensing of trade secret data has been successfully accomplished through amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in 1972 and 1978. Under current law, when pesticide research data submitted to EPA are considered by the agency in support of another company's registration, compensation of the company that first submitted the data is required. Initially, EPA hearing examiners determined what constituted "reasonable" compensation; this responsibility was transferred to private arbitrators in 1978.

FIFRA's mandatory data licensing and compensation scheme has survived a constitutional challenge as a governmental "taking" of private property without just compensation in violation of the Fifth Amendment. Ruckelshaus v. Monsanto Co. In Thomas v. Union Carbide Agricultural Products Co., the Supreme Court concluded that the delegation of adjudicatory power to arbitrators, rather than the courts, did not violate the "separation of powers" required by the Constitution.

- **Recommended Changes**

Legislation implementing this proposal must be carefully crafted to ensure that --

1. *FDA is provided the authority, and the resources, to establish an appropriate means of measuring risk, and determining reduced risk.*

2. *Approval by FDA as a "reduced risk" product must be based on both reduced risk and whether it makes a contribution to reducing addiction.*

3. *The "reduced risk" program should be balanced by efforts to facilitate, and expedite, development and approval of pharmaceutical products to treat tobacco dependence.*

AMERICAN CANCER SOCIETY**ANALYSIS OF REMAINING TERMS OF
THE PROPOSED TOBACCO SETTLEMENT****VIII. AG'S RECOMMENDED ALLOCATION OF PUBLIC HEALTH FUNDS**

- **Summary of Settlement Provisions (pp. 36-38)**

Of the \$368.5 billion in payments that will be received from the tobacco companies over twenty-five years, the Agreement recommends that approximately \$93 billion, or roughly 25% of the total payments, be used to fund public health programs, as follows:

- HHS will receive \$125 million for the first three years, and \$225 million annually thereafter to fund youth prevention, adult cessation, research and other programs.
- FDA will receive \$300 million annually to carry out its obligations and to enforce the provisions of this settlement.
- State and local governments will receive \$75 million for the first two years, \$100 million the third year, and \$125 million annually thereafter to fund community-based prevention programs.
- \$100 million per year will be dedicated to fund research and development of tobacco prevention and cessation methods.
- Sports teams and events that lose tobacco industry sponsorship will receive \$75 million per year for the first 10 years following the effective date of the settlement. After 10 years, these funds will be reallocated to other public health programs.
- An independent, non-profit organization to be formed will receive \$500 million per year to fund multi-media public education campaigns.
- A newly formed Tobacco Cessation Trust Fund will receive \$1 billion per year for the first four years and \$1.5 billion per year thereafter. The fund, which will be managed by the Secretary of HHS, will be used to assist existing smokers in their efforts to quit smoking.
- A Public Health Trust Fund under the control of a Presidential Commission will receive \$25 billion to fund specific tobacco-related medical research. Representatives from the

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public health community and state Attorneys General will serve on the Commission.

- **ACS Analysis**

Overall, these provisions appear promising, but they represent only the recommendations of the participating state Attorneys General. Ultimately, the President and Congress will be charged with deciding how to allocate these funds. The ACS is confident that the President and Congress will perform this function faithfully, holding the best interests of the national public health as its foremost objective.

Of greater concern, however, is the fact that these provisions only account for approximately 25% of the total industry payments. The settlement does not explicitly provide for the allocation of the remaining 75% of the payments. Presumably, these funds will be used to settle certain private law suits, to pay legal fees, and to compensate states for tobacco-related Medicaid costs.

- **Recommended Changes**

The ACS would prefer to have a greater percentage of the industry payments explicitly devoted to fund public health programs. Congress should conduct hearings to determine how much funding is needed for these public programs and which programs are most effective in achieving the stated public health goals.

While the ACS trusts that states will use the unallocated funds to pay for tobacco-related medical expenses and public health programs, the ACS believes that the settlement should provide greater detail regarding how the unallocated funds are to be used.

IX. NATIONAL TOBACCO CONTROL PROTOCOL AND CONSENT DECREES

- **Summary of Settlement Provisions (pp. 27-28)**

In order to insure that the settlement will benefit all states, including those that are not participating in the settlement, the industry will enter into a "national tobacco control Protocol" (the "National Protocol") that will embody certain terms of the Act. The National Protocol will be a binding contract enforceable by the federal government and all states, and it will not be subject to facial constitutional challenge.

In addition, the tobacco industry and the participating states will enter into consent decrees, that will reiterate, in identical language, the terms of the Act governing:

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1. advertising, marketing, and youth access restrictions;
2. trade associations;
3. lobbying restrictions;
4. disclosure of tobacco smoke constituents;
5. disclosure of non-tobacco ingredients;
6. disclosure of industry research "relating to health, toxicity and addiction;"
7. compliance and corporate culture;
8. payments to the states;
9. obligations to deal only with complying distributors/retailers;
10. warnings, labeling and packaging; and
11. dismissal of other pending litigation specified by the parties.

The consent decrees will not include the terms of the agreement governing:

1. product design, performance or modification
2. manufacturing standards and good manufacturing practices
3. testing and regulation of toxicity and ingredients approval; and
4. the national FDA look back provisions.

The settlement requires that the consent decrees be construed in conformance with the Act and the National Protocol, and with each other. The parties shall expressly waive all constitutional challenges to the consent decrees, and the terms of the consent decrees shall remain binding upon the parties even if corresponding provisions of the Act are declared unconstitutional.

- **ACS Analysis**

Although the content of the National Protocol is not clearly defined, this provision will serve the important function of extending the settlement to the ten non-participating states. Thus, the ACS supports this provision as a means of establishing and maintaining a nationally unified campaign to reduce tobacco use and improve public health.

The ACS also supports the Consent Decree provisions because they provide an important "back-up" system which will remain effective even if portions of the Act are declared unconstitutional. Although the parties to the settlement will not have standing to challenge its constitutionality, the Act is likely to face numerous constitutional challenges from third parties.

- **Recommended Changes**

The consent decrees must also provide for the achievement of agreed-upon public health goals as a "safety net" in case federal legislation flounders.

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Congress should also require the parties to submit draft consent decrees and a draft National Protocol in the early stages of developing federal legislation so Congress can determine whether these three pieces "fit" together, and determine how conflicts in enforcement, claimed rights, and procedures can be resolved.

X. LICENSING OF RETAILERS

- **Summary of Settlement Provisions (pp. 12-13)**

The provisions to eliminate youth access to cigarettes and smokeless tobacco are enhanced by a requirement that the Federal government establish minimum standards for a retail licensing program financed through funding provided by industry payments. The licensure program would apply to all manufacturers, distributors, wholesalers, retailers, and importers of tobacco products. It would be enforced by federal, state and local authorities. The new licensing program:

- Prohibits the sale of tobacco products to consumers by an unlicensed seller;
- Requires that applicants and holders of a license comply with all federal statutes and regulations governing tobacco products;
- Imposes licensing fees to cover costs incurred by states to administer the licensing program;
- Establishes comparable Federal licensing provisions for the military and other U.S. Government operations and for Indian tribes.

The settlement also specifies penalties for violation of the licensing laws. Any person who sells tobacco products without a license is subject to criminal sanctions, including a \$1,000 fine, six months imprisonment, or both. For corporations, the settlement calls for a maximum fine of \$50,000. States may impose more severe penalties than those set forth under federal law.

Civil sanctions for violating state licensing laws governing the sale of tobacco to minors could result in fines and license suspension or revocation, depending on the number of offenses committed within a two-year period. Each state must enact an enforcement scheme that provides "substantially similar standards" to the federal minimum. Civil penalties are as follows:

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<u>Offense w/in 2 yr. pd</u>	<u>Maximum Civil Penalty</u>
First	\$500. 3 day license suspension, or both
Second	\$1,000, 7 day suspension, or both
Third	\$2,000, 30 day suspension, or both
Fourth	\$5,000, 6 month suspension, or both
Fifth	\$10,000, one year suspension, or both
Sixth - Ninth	\$25,000 or mandatory revocation for 3 years
Tenth	Mandatory license revocation

- **ACS Analysis**

If adequately funded and administered, a national licensing system can help reduce illegal sales to minors. However, research of local enforcement schemes for both tobacco and alcohol demonstrate that license suspension and revocation are much more effective deterrents to reducing illegal sales to minors than financial penalties.

While states may impose more severe criminal penalties, the civil penalties are clearly stated and states are required to enact laws imposing similar penalties. This penalty scheme would expressly preempt more stringent and effective state and local sanctions, such as required license revocation.

The requirement that state and local governments enforce the licensure provisions would be allowed under tenth amendment analysis. In Printz v. United States and New York v. United States, the Supreme court makes clear that the federal government may not commandeer states to carry out federal objectives, despite Congress' power to pass laws under the Commerce Clause. That is, the federal government cannot impose unfunded mandates on states. However, in this case, the requirements are funded by tobacco industry payments, and therefore, the provisions requiring enforcement of licensure provisions are Constitutional.

- **Recommended Change**

Delete the option of financial penalties for second and subsequent offenses, make the escalating schedule of suspensions mandatory, and require license revocation after the third offense.

XI. NATIONAL CLEAN INDOOR AIR STANDARDS

- **Summary of Settlement Provisions (pp. 30-31)**

The proposed settlement agreement restricts indoor smoking in "public facilities" (a building entered by 10 or more people at least one day per week) to

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negatively pressurized areas ventilating directly to the outside. Employees shall not be required to enter the smoking area while smoking is occurring. Restaurants (other than "fast food restaurants"), bars, private clubs, hotel guest rooms, casinos, bingo halls, tobacco merchants and prisons are exempted. The settlement would require OSHA to issue regulations to implement and enforce these standards, with enforcement costs paid by the industry, but would become effective within one year regardless of OSHA's actions. *fine*

The act would not preempt or otherwise affect any other state or local law that impose the same or more stringent restrictions on smoking in public facilities. Similarly, the agreement does not preempt or otherwise affect any federal rules that restrict smoking in federal facilities.

- **ACS Analysis**

These provisions summarize H.R. 1771, "To Amend the Public Health Act to Protect the Public from Health Hazards Caused by Exposure to Environmental Tobacco Smoke," introduced by Representative Waxman on June 3, 1997. There is no federal preemption provision in the bill.

- **Recommended Change**

The ACS supports H.R. 1771 and recommends its adoption as part of the legislation implementing the settlement agreement. See section III on ACS recommendations regarding preemption.

XII. RESTRICTIONS ON MARKETING AND ADVERTISING

- **Summary of Settlement Provisions (pp. 8-9)**

The Settlement proposal includes the following restrictions on marketing and advertising:

- Authorize only black and white, text-only ads in publications with 15%+ youth readership;
- Ban brand-name event sponsorship, such as concerts and sports;
- Ban all billboards, outdoor signs, and signs in arenas;
- Ban all human images and cartoon characters from advertising and packaging;
- Ban advertising on non-tobacco products, like caps, jackets and bags;

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- Ban use of non-tobacco brand names on tobacco products;
 - Ban offers of non-tobacco items or gifts based on proof of purchase;
 - Require ads to carry FDA-mandated statement "Nicotine Delivery Device;"
 - Prohibit point-of-purchase ads in all facilities other than adult-only stores and tobacco outlets (with very limited exceptions);
 - Ban advertising on the Internet, unless "designed to be inaccessible in or from the [U.S.];"
 - Prohibit payments to place products in movies, TV programs and video games, or "to 'glamorize' tobacco use in media appealing to minors," including records and concerts;
 - Require disclaimer in ads with "product descriptors (e.g., 'light' or 'low tar')"; and
 - Require FDA review of all new ads and labels concurrent with introduction.
- **ACS Analysis and Recommended Changes**

Overall, ACS strongly supports all of the proposed marketing and advertising restrictions, which appear to have the potential to impact public health in a positive way. However, there are several shortcomings and weaknesses that need to be corrected.

1. In the first five years, the FDA may alter or strengthen these marketing restrictions only under "extraordinary circumstances," even though the industry may develop new, unanticipated or even unintentional marketing techniques that continue to appeal to minors.

Recommended Change: *Delete the condition that FDA can make changes only under "extraordinary circumstances".*

2. Cigars and pipes are exempt from advertising restrictions, even though cigar use among minors is climbing fast.

Recommended Change: *Apply the advertising and marketing restrictions to "all tobacco products."*

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3. The industry may continue using traditional product "descriptors" such as "light" and "mild" simply by adding a disclaimer in their ads, even though surveys show 60% of smokers wrongly believe such cigarettes are less harmful. On the other hand, a new and genuine reduced-risk product may not list such claims unless the manufacturer "demonstrates scientifically" that the product "significantly" reduces health risk.

Recommended Change: *Require traditional product "descriptors" like "light" and "mild" to meet the same health claim standards established for new, reduced-risk products.*

XIII. RESTRICTIONS ON YOUTH ACCESS TO TOBACCO

- **Summary of Settlement Agreement (pp. 11-12)**

Under the settlement agreement, FDA would be provided explicit authority to:

- Ban sales to kids under 18;
- Require photo i.d. for anyone under 27 and a face-to-face transaction;
- Ban all vending machines;
- Require minimum pack of 20;
- Ban sale of single cigarettes and free samples;
- Prohibit mail order sales except with proof of age, with FDA review after two years; and
- Ban self-service displays, except in adult-only facilities, and tobacco must be behind the counter, under lock, or if on the counter not visible or accessible.

- **ACS Analysis**

ACS strongly supports these needed measures, but recognizes that without adequate enforcement, they will be of little use. Recently, Congress cut the administration's proposed budget for enforcing the current FDA rule from \$34 million to \$15 million.

- **Recommended Change**

Insure that industry funds earmarked for enforcement may not be cut by appropriations committees.

AMERICAN CANCER SOCIETY**XIV. WARNINGS, LABELING AND PACKAGING**

- **Summary of Settlement Provisions (pp. 9-11)**

Under the settlement agreement, manufacturers of cigarette packs would be required to rotate eight explicit warnings, including "cigarettes are addictive," "cigarettes cause cancer," and "smoking can kill you" on a large label covering 25% of the upper front panel. Smokeless tobacco would carry four similar warnings. Warnings must cover 20% of all advertisements. FDA may "require label and advertising disclosures relating to 'tar' and nicotine, [and] disclosures by other means relating to other constituents."

- **ACS Analysis**

These are significant improvements over the existing warning labels. However, under the proposal:

1. Only the front of packages require warnings.
2. Industry package designers may develop new ways to minimize the impact of the warning labels.

- **Recommended Changes**

1. *Require warnings on the back of packages as well.*
2. *Require FDA to issue regulations on warning labels that prevent manufacturers from using packaging or design techniques that reduce the impact of the warnings.*

AMERICAN CANCER SOCIETY**ECONOMIC ANALYSIS OF THE
PROPOSED TOBACCO SETTLEMENT 1/**

It has been widely reported that U.S. cigarette manufacturers will be required to pay a total of \$368.5 billion during the first 25 years of the tobacco industry-wide Proposed Resolution. 2/ This characterization of the settlement payments, however, substantially overstates the real value of the amount that will actually be paid.

- The reported 24-year total of \$368.5 billion does not take into account the "adjustment for volume" provisions in the Proposed Resolution. 3/ This provision essentially pegs all payments to the volume of cigarettes sold, and therefore renders the payment scheme equivalent to a unit tax on cigarettes. As the Proposed Resolution contemplates, 4/ this virtual tax will be passed on to consumers in the form of higher prices. As a result, the volume of cigarettes sold will decline, and therefore total industry payments will decline, too.
- Based on a conservative economic model of the relation between cigarette consumption and cigarette prices, 5/ I estimate that the real price of a pack of cigarettes (in 1996 dollars) will rise by \$0.41 per pack in 1996 dollars at the outset. This virtual tax will gradually increase to \$0.62 per pack (in 1996 dollars) by the fifth settlement year, and remain at that level indefinitely.

1/ Prepared by Jeffrey E. Harris, M.D., Ph.D. of the Massachusetts Institute of Technology and Massachusetts General Hospital. The views expressed here are those of the author. They do necessarily represent the position of the Massachusetts Institute of Technology or the Massachusetts General Hospital.

2/ "Proposed Resolution: For Settlement Discussion Purposes Only. 6/20/97, 3:00 p.m. DRAFT." 68 pp.

3/ "Proposed Resolution... Title VI, B5," at p. 34.

4/ "Proposed Resolution... Title VI, B7," at p. 35.

5/ See Harris, J.E. "Comments on: Proposed Resolution: For Settlement Discussion Purposes Only. 6/20/97, 3:00 p.m. DRAFT." 68pp." Commissioned by the American Cancer Society, June 26, 1997. My model assumes that current price elasticity of demand is -0.4, and that, even in the absence of price increases, cigarette consumption will decline at a background rate of 0.6% annually.

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- If the virtual tax is fully passed on to American smokers, as I expect it will, then total U.S. cigarette consumption will fall from 24.2 billion packs annually to 22.3 billion packs in the base year of the settlement, and continue to decline gradually to 18.4 billion packs by the 25th year. Applying the volume adjustment provision, I estimate that the face value of industry payments would amount to \$304.3 billion over 25 years. 6/
- The face value of industry payments, however, does not reflect their *present discounted value*, that is, the amount that investors would be willing to pay today for a portfolio of 25-year corporate bonds that promised to pay exactly what the Proposed Resolution mandates. Based on an interest rate comparable to the long-term rates on corporate bonds and U.S. Treasury obligations, I estimate that the present discounted value of volume-adjusted industry payments would be \$194.5 billion over 25 years. 7/

The Proposed Resolution imposes financial penalties on cigarette manufacturers if the proportion of 13- to 17-year-olds who smoke cigarettes every day does not reach specified target levels within 5 to 10 years. 8/ While economic research suggests that teenagers' smoking rates may be especially responsive to price, the increase in cigarette price anticipated from the Proposed Resolution would be insufficient by itself to reach the specified targets.

- Based upon my analyses of data from the University of Michigan's "Monitoring the Future" Study, I estimate that the "base percentage" of underage daily smokers (that is, the 1986-1996 historical average) is 15.2% 9/

6/ This computation does not include the drop in Federal excise tax revenues and state excise and sales tax revenues on cigarettes that would result from falling cigarette consumption. For example, even if states raised their excise and sales taxes to keep pace with inflation, the loss in state revenue would have a face value of \$43.2 billion over 25 years.

7/ My calculations of present discounted value took into account the "inflation protection" provision (Tile VI, B.4) of the Proposed Resolution.

8/ See Appendix V of the Proposed Resolution.

9/ See "Monitoring the Future" Study. *Cigarette Statistics Table I: Long-Term Trends in Prevalence of Cigarettes for Eighth, Tenth, and Twelfth Graders*. Ann Arbor: Univ. Michigan, 1997. I estimate the base percentages to be: 8.5% for 8th graders; 14.7% for 10th graders; and 19.2% for 12th graders. The population-weighted average, as specified in Appendix V, A.1 of the Proposed Resolution, would then be 15.2%.

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Hence, the five-year goal of a 30% reduction in underage smoking prevalence would mean a target rate of 10.6% daily smokers. This target actually amounts to a 58% reduction from the current 1996 prevalence of 18.2% among eighth- to twelfth-graders. 10/

- Based upon the most recent economic research on the responsiveness of youth smoking to increases in cigarette prices, 11/ I estimate that the expected \$0.62 increase in the real price of cigarettes would translate into an 18% reduction in teenage smoking from its 1996 level, that is, to about 14.9% daily smokers, which is well above the calculated target rate of 10.6% daily smokers. 12/

I compared the effect of the Proposed Resolution on cigarette consumption and governmental revenues with that of an inflation-adjustable increase in the Federal excise tax on cigarettes. A \$1.00-per-pack tax, levied by Congress in the base year and adjusted to keep pace with inflation, would yield approximately 60% more revenues over 25 years than the Proposed Resolution. An inflation-adjusted \$1.50-per-pack tax would yield more than twice the revenues expected from the Proposed Resolution. A \$1.50-per-pack price increase, I estimate, would be sufficient by itself to reduce the 13- to 17-year-old daily smoking rate to the target level contemplated by the Proposed Resolution.

10/ The 1996 rates of daily smoking in the "Monitoring the Future" Study were: 10.4% for 8th graders; 18.3% for 10th graders; and 22.2% for 12th graders. The population-weighted average, as specified in Appendix V, A.1, would then be 18.2% for 1996.

11/ See Chaloupka FJ, Grossman M. "Price, Tobacco Control Policies and Youth Smoking," Working Paper No. 5740. Cambridge MA: National Bureau of Economic Research, Sept. 1996. These authors estimated the "participation price elasticity," which captures the effect of price on the proportion of youth who smoke, to be -0.6. The "overall price elasticity," which also includes the effect of price on the number of cigarettes that youth smokers consume, was estimated to be -1.3.

12/ Under the surcharge provisions of Appendix V, the resulting smoking prevalence would amount to only a 2% reduction from the "base percentage" of 15.2%. Hence, the reduction in underage smoking rates would fall 28 percentage points below the 30-percent target. While provisions B.1(b)(1)-(3) of Appendix V (pp. 53-54) are complex, it appears that the resulting surcharge would reach the \$2 billion cap imposed by provision B.1(b)(4)(p.54). If this surcharge were passed onto all consumers in the form of higher retail prices, the effect would be about \$0.08 per pack.

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- If Congress raised the cigarette excise tax by \$1.00 per pack and periodically revised the tax to keep pace with inflation, then the face value of industry payments would be \$480.1 billion over 25 years, as compared to \$304.3 billion under the Proposed Resolution. The present discounted value would be \$314.4 billion, as compared to \$194.5 billion under the Proposed Resolution. By year 24, total U.S. cigarette consumption would be 17.1 billion packs, as compared to 18.4 billion under the Proposed Resolution. The daily smoking rate among 13- to 17-year-olds would decline to 12.9%, as compared to the 14.9% rate expected under the Proposed Resolution. 13/
- If Congress raised the cigarette excise tax by \$1.50 per pack and periodically revised the tax to keep pace with inflation, then the face value of industry payments would be \$653.2 billion over 25 years, as compared to \$304.3 billion under the Proposed Resolution. The present discounted value would be \$427.8 billion, as compared to \$194.5 billion under the Proposed Resolution. By year 25, total U.S. cigarette consumption would be 15.5 billion packs, as compared to 18.4 billion under the Proposed Resolution. 14/ Thus, an inflation-adjustable tax of \$1.50 per pack would, by itself, result in a decline in youth smoking sufficient to achieve the target rate of 10.9% contemplated by the Proposed Resolution.

13/ Since cigarette consumption would decline, there would be a reduction in state excise and sales tax receipts equal to \$59.6 billion in face value and \$37.0 billion in present discounted value over 25 years. See footnote 6.

14/ Since cigarette consumption would decline, there would be a reduction in state excise and sales tax receipts equal to \$77.5 billion in face value and \$48.7 billion in present discounted value over 25 years. See footnote 6.



National Government Relations Office

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AMERICAN CANCER SOCIETY

POSITION ON THE PROPOSED

TOBACCO SETTLEMENT

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AMERICAN CANCER SOCIETY**INTRODUCTION**

The American Cancer Society (ACS) believes that the settlement process between 40 Attorneys General and the tobacco industry provides a rare opportunity to make substantial inroads in combating tobacco related illnesses -- the largest cause of death and disease in the United States. More importantly, the proposal has the potential to reverse the frightening increase in teenage tobacco use.

Perhaps because the settlement proposal was adopted without the benefit of significant public scrutiny or debate, it is clear that as currently presented, the settlement is flawed. It includes, in our view, obvious shortcomings that must be addressed by Congress to effectuate important tobacco control policies. We believe that, using the proposed settlement as a platform, Congress can craft balanced legislation that resolves most litigation and ensures adequate public health protection from the devastating effects of tobacco use.

The proposed settlement must be viewed in the context of the devastating effects of tobacco use on health and the continued attempts at the federal, state and local levels to address this important public health problem. Our nation took an important step toward mitigating the harm of tobacco use through the adoption of advertising restrictions and warning labels in the 1960s. Since that time, states have taken the lead in tobacco control through imposing excise taxes on cigarettes and tobacco products, banning billboards, requiring ingredient disclosure, and through policies aimed at protecting non-smokers from the secondary effects of smoking in public places and controlling underage access to tobacco products. The settlement proposal offers the opportunity to build upon these state and local efforts to establish a national policy for tobacco control with a primary goal of protecting our children from ever starting to smoke. ~~However, no single piece of Federal legislation can represent a permanent, long-term approach to the problem of tobacco use.~~ The American Cancer Society will continue to work for adoption of even stronger tobacco control policies by Congress, state legislatures, local governments, and public health officials.

Despite state and local efforts to control underage use of tobacco, the U.S. has witnessed a disturbing increase in the rate of teenage tobacco use. Over 3,000 teenagers become hooked on tobacco for the first time every day. Although the tobacco industry has consistently denied that it attempts to encourage teenage tobacco use, empirical evidence suggests that advertising in youth-oriented publications, use of cartoon characters in advertising, and the steady display of young, healthy models in tobacco advertising all have the effect of increasing rates of teenage tobacco use. The settlement proposal represents an opportunity for Congress to enact legislation to address the problem of underage tobacco use

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through advertising restrictions, education efforts, and industry incentives to decrease the rate of tobacco use among minors.

One of the most pernicious aspects of tobacco products is the addictive effect of nicotine. The scientific community unanimously agrees that nicotine has powerful addictive properties. Indeed, we now know that the tobacco industry has been fully aware of these properties for decades. Reducing or even eliminating nicotine from tobacco is critical to any effective tobacco control policy. The proposed settlement attempts to address this issue through the regulation of tobacco product development and manufacturing. Congressional action on control of nicotine should expand the authority of FDA to regulate the sale, manufacture and marketing for all tobacco products including cigars and pipe tobacco.

The American Cancer Society believes that any evaluation of the settlement proposal must consider the following questions: Is the FDA given appropriate tools to effectuate critical public health goals through regulation of tobacco products? Are regulators, and the public, given appropriate access to industry information on the health effects of tobacco? Are the roles of state and local governments in implementing tobacco control policies properly enhanced and preserved? Does the proposal include sufficient incentives for the reduction of tobacco consumption and the development of less hazardous products?

These recommendations are, to a large extent, based upon the Analysis and Review of the Tobacco Settlement that was also drafted and disseminated by the ACS. Based on the work of experts in law, economics, medical ethics and public health, the Analysis and Review includes separate sections on: a summary of the current FDA rule; a special legal analysis of the United States District Court case upholding, in part, the FDA rule; a special legal analysis of the proposed authority for the FDA to regulate nicotine content of tobacco products; an economic analysis of the rule; and a discussion of important constitutional issues raised by the settlement. In addition, we provide important factual information about public health and tobacco. Specific information in these documents supplements our recommendations.

The following document outlines our recommendations for the Congressional response to the settlement proposal. Most, but not all, provisions are analyzed. We have placed the most emphasis on seven principal provisions which we believe are the most important to public health. Our review includes a summary of the various provisions, an analysis of them, and recommended changes to legislation that would implement the proposed settlement. We invite critical comment and analysis of our findings and recommendations and look forward to working with our colleagues in efforts to develop what could become the most important public health legislation enacted in this century.

AMERICAN CANCER SOCIETY**ANALYSIS OF PRINCIPAL TERMS OF
THE PROPOSED TOBACCO SETTLEMENT****I. INDUSTRY PAYMENTS**

- **Summary of Settlement Provisions (pp. 34-35)**

The settlement requires the tobacco industry to make total payments of \$368.5 billion (in unadjusted dollars) over 25 years. This amount includes a lump sum payment of \$10 billion due immediately upon the signing of the statute, followed by annual base payments ranging between \$8.5 billion and \$15 billion. The amount of each year's scheduled base payment will be increased over the previous year's payment by the greater of 3% or the Consumer Price Index ("CPI"). In addition, the payments shall be adjusted according to changes in the domestic volume of tobacco product sales. Any decrease in the scheduled annual payment, however, will be offset by a surcharge of 25% of any increase in the industry's profits from domestic sales compared to its "base year" profits.

In order to maximize the reduction in youth tobacco use, the settlement requires tobacco manufacturers to pass on the costs of these payments to tobacco consumers by increasing product prices. The settlement will permit tobacco companies to deduct these expenses from their federal income tax liabilities as ordinary and necessary business expenses.

- **ACS Analysis**

From a public health perspective, the substantial industry payments are highly desirable as a means of funding public health programs. In addition, the requirement that tobacco companies pass along the payments to consumers in higher prices will likely reduce tobacco consumption almost immediately, especially among minors. The proposal, however, has several serious shortcomings that must be addressed.

First, the amount of the required industry payments may be too small to produce significant reductions in youth tobacco use. In his recent economic analysis of the settlement, Professor Jeffrey E. Harris, M.D., Ph.D. of the Massachusetts Institute of Technology and Massachusetts General Hospital concludes that the present discounted value of the required \$368.5 billion payments is actually only \$194.5 billion. ^{1/} As a result, Dr. Harris argues that the payments

^{1/} Harris, J.E., Economic Analysis of the Proposed Settlement, American Cancer Society Analysis and Review of the Tobacco Settlement, July 24, 1997. This analysis is at Tab 16 of the ACS Analysis and Review.

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would produce a 41-cent per pack increase in the price of cigarettes in Year One. This price increase would gradually grow to 62 cents per pack (in 1996 dollars) by Year Five and would remain at that level indefinitely.

Secondly, the tax treatment of settlement costs will further reduce the economic impact upon the tobacco industry and will have a negative impact upon federal income tax revenues. Because the required payments are tax deductible to the tobacco companies, the payments will reduce the industry's federal income tax liability and will reduce the governments revenue receipts. Thus, much of the burden of the required payments would be transferred from the tobacco industry to the federal government, partially transforming the settlement into a federally funded program.

There is widespread agreement among health economists and policy analysts that almost no other public health strategy would exhibit the speed and cost-effectiveness of impact achieved by increasing the price of tobacco products. Increases in price will decrease both participation (the number of smokers) and daily consumption amounts (the number of cigarettes per person per day). Economists have estimated that a 10% increase in the price of cigarettes will reduce overall smoking among adults by about 4% and will reduce smoking initiation by about 6.75% among minors (this does not include decreases in consumption among minors).

Many public health advocates, including the Koop/Kessler commission have argued that an even larger price increase, as much as \$2 per pack, is desirable to reduce tobacco consumption as much as possible while still remaining economically feasible. In previous research, Dr. Harris concluded that the tobacco industry could sustain price increases of more than \$2 per pack and that it could afford to make damage payments sufficient to produce such price increases. By producing only a 62-cent price increase, the settlement falls far short of the possible reduction in youth tobacco use that can be attained by a greater increase in price.

- **Recommended Change**

Congress must design a payment scheme that will raise the price of tobacco products by requiring additional payments to be made by the industry and/or consumers of tobacco. This will have the effect of collecting additional money for compensation and for public health programs and will fulfill the more important goal of decreasing the youth tobacco consumption rate as much as possible. We strongly recommend that, as part of legislation implementing the proposed settlement, the cigarette excise tax should be raised by at least \$2.00, with proportionate increases in the tax on cigars and pipe tobacco.

AMERICAN CANCER SOCIETY**II. FDA REGULATION OF NICOTINE AND OTHER TOBACCO CONSTITUENTS****• Summary of Settlement Provisions (pp. 15-18)**

For *twelve years*, the FDA is permitted to adopt performance standards that require the modification of existing tobacco products, including a gradual reduction (but not the elimination) of nicotine and the possible elimination of other harmful components of tobacco products. These modifications may be required based on a finding that such changes:

- (a) will significantly reduce health risks;
- (b) are technologically feasible, and
- (c) will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard.

The authority to require any product modification during this initial twelve-year period must be based on a showing of "substantial evidence" that is documented in an administrative record and developed through a formal rulemaking process, including a hearing. Manufacturers of tobacco products that would be affected by any proposed modification have a right of judicial review. Congress also may intervene if it so chooses.

After the initial twelve year period, the FDA is permitted to set product safety standards that go beyond the standards it is authorized to set during the first twelve years. Specifically, the FDA is permitted to require the alteration of tobacco products, including the elimination of nicotine or other harmful components of tobacco products based on a finding that:

- (a) the safety standard will result in a significant overall reduction of the health risks to tobacco consumers as a group,
- (b) the modification is technologically feasible, and
- (c) the modification will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard.

According to the agreement, given the significance of such an action, the FDA may require the elimination of nicotine based on a "preponderance of the evidence" pursuant to, at a manufacturer's election, a hearing or notice and comment rulemaking with a right of judicial review. Furthermore, any such action must be phased in, and the phase-in period may not begin for two years in order to permit Congressional review.

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Importantly, in any judicial review of the FDA's action, deference to the FDA's findings will depend on the extent to which the matter at issue is within the agency's field of expertise.

- **ACS Analysis**

The 1996 FDA rule asserted the agency's jurisdiction over cigarettes under the current medical device law. A federal district court affirmed this assertion of authority in the Coyne Beahm case. Because the FDA rule does not seek to control the development or manufacturing of tobacco products or impose limitations on the nicotine content of these products, the district court decision did not address the specific question of whether FDA can impose these restrictions.

The ACS believes that the procedural hurdles imposed by this section are wholly unjustified from a legal or public health perspective. Requiring the FDA to engage in "formal rule making" before it can adopt performance standards to modify tobacco products (including reduction of nicotine) may enable a single tobacco company to complicate and encumber the administrative process for years in order to delay a rule from going into effect. Additionally, the burden on the agency to demonstrate that it meets specified statutory findings by a "preponderance of the evidence" before it may ban nicotine altogether introduces a new, and presumably higher, standard into administrative law proceedings. Finally, it would be difficult for FDA to demonstrate the negative finding that "significant demand for contraband products" will not result from changes to current tobacco products. This requirement could be interpreted to prevent the ~~FDA from acting even~~ if the benefits of the rule far exceeded the costs of black market sales in high nicotine cigarettes.

- **Recommended Changes**

1. *Specifically authorize FDA, after notice and opportunity for comment under 5 U.S.C. § 553, to develop performance standards for tobacco products designed to reduce or eliminate any constituent, including nicotine.*
2. *Delete the provision governing FDA activities after 12 years and apply a single standard that would apply from the effective date of the Act forward as follows.*
3. *Eliminate the proposed heightened standards of proof ("substantial evidence" and "preponderance of the evidence") required for agency action and allow traditional administrative law to apply.*

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4. *Delete requirements that FDA demonstrate that any modification in tobacco products must be based on a finding that the modification will not result in significant contraband.*
5. *Federal requirements to reduce nicotine must apply to cigars and pipe tobacco, as well as cigarettes.*

III. PUBLIC DISCLOSURE OF PAST AND FUTURE INDUSTRY DOCUMENTS

- **Summary of Settlement Provisions (Appendix VIII, p. 64)**

The settlement requires manufacturers to establish and maintain a centralized depository for documents "produced" in pending litigation. The documents will be available to Congress, state and federal agencies, and the public under certain conditions. The industry is permitted, however, to withhold any documents it considers to be "privileged" and any materials it considers to represent trade secrets. Materials regarding research on health, safety and less hazardous products also will be included, with the exception of legitimate trade secrets.

Upon settling the AG suits, the companies are permitted to re-review all documents claimed as privileged and create a new inventory of privileged documents. Anyone wishing to challenge the industry's assertion of privilege or trade secret must file a claim, which will be decided by a three-judge panel.

- **ACS Analysis**

It is clear that the tobacco industry has not disclosed all it knows about the dangers and addictive properties of tobacco products. During a period when millions of Americans contracted lung cancer or other tobacco-induced diseases, the industry did not release its own internal research regarding the harmful effects of tobacco use. Thus, complete disclosure of industry research regarding the effects of tobacco use is essential to a national tobacco control policy.

The settlement proposal provides no explicit deadline for the production of the limited number of documents the industry has already agreed to produce. More importantly, the settlement does not compel tobacco manufacturers to turn over hundreds of thousands of documents, representing millions of pages, currently protected by attorney-client privilege. Many of these documents might have come to light through litigation. The documents are believed to contain incriminating evidence on marketing research, strategies to induce teenagers to use tobacco products, studies on the health dangers of tobacco, and political strategies.

Although the settlement proposal includes a mechanism for resolving disputes over privileged documents, this process is overly cumbersome and

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extremely time-consuming. Companies could potentially stall review of any challenged material through the three-judge panel by insisting on a line-by-line review of the documents. Thus, what is potentially the most critical information may not reach the public for years, if ever.

The ACS believes that all information on the harmful effects of smoking -- whether or not it is privileged or trade secret information -- should be provided to FDA for use in development of Product Standards and reduced risk products. The FDA has strict requirements relating to non-disclosure of trade secrets and has vast experience in regulating products on the basis of confidential information to review documents that are currently protected under attorney-client privilege or are trade secrets.

A • **Recommended Changes**

1. Congress should ensure that both state and federal courts have jurisdiction to quickly resolve privilege claims. The burden should be on industry to demonstrate why documents should not be disclosed.
2. Federal legislation regarding disclosure of industry documents should also explicitly require the industry to release to the FDA all information -- including research and marketing data -- that is relevant to public health, safety, and the development of less hazardous tobacco products.

IV. SCOPE AND EFFECT / PREEMPTION

- **Summary of Settlement Provisions (pp. 32-33; 26-27)**

The settlement preserves state and local authority to:

- (a) restrict or eliminate underage access to and consumption of tobacco;
- (b) further restrict or eliminate ETS exposure in the workplace and "other public and private places and facilities;" and
- (c) restrict or eliminate the sale or distribution of tobacco products.

The terms of the settlement document "preserve" current federal law providing for national uniformity of warning labels, packaging and labeling requirements and advertising and promotion requirements related to tobacco and health. In addition, the preemption provisions of section 521 of the Food, Drug, and Cosmetic Act (FDC Act), designed to provide uniform regulation of medical devices, would apply to tobacco products since they will be regulated as devices.

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However, under the "Penalties and Enforcement" provisions of the settlement proposal, state enforcement actions may not impose obligations beyond those imposed by the Act (except where the Act does not specifically preempt additional state law obligations) and is limited to the penalties listed. Thus, it appears that the settlement would preempt state and local laws with respect to penalties and enforcement.

- **ACS Analysis**

The Federal Cigarette Labeling and Advertising Act (the "Labeling Act") requires cigarette manufacturers to include specified warning labels on cigarette packages, and it bans cigarette advertising on television, radio, and other media subject to the jurisdiction of the Federal Communications Commission. The Labeling Act also contains a provision preempting state and local laws to the extent that they impose: (1) a requirement or prohibition, (2) based on tobacco use and health, (3) with respect to advertising or promotion. (See Cipollone v. Liggett Group, Inc.). All three of these criteria must be met in order for the state or local law to be preempted.

Although the Labeling Act's preemptive force has been construed narrowly by the United States Supreme Court, many state and local regulations fall under its scope. For example, any state or local regulation which restricts tobacco advertising or promotions with the goal of protecting health is preempted. In addition, many common law tort claims are preempted. For example, if a plaintiff claims that post-1969 advertising or promotions should have included additional, or more clearly stated warnings or information, these claims are preempted by the Labeling Act.

Similarly, in Medtronic, Inc. v. Lohr, the court narrowly construed the preemption provisions of the FDC Act, which preempts requirements that are "different from, or in addition to any requirement applicable under this Act to the device" and which relate to safety or effectiveness of the device or other matter included in such requirement. Noting that throughout our history, the states have exercised their police powers to protect the health and safety of their citizens "because these are 'primarily and historically . . . matter[s] of local concern'" the court held that the provision does not preempt state common law negligence actions. The court appears to hold that only if FDA promulgates a requirement, and a state imposes a specific duty on a device manufacturer that is "different from, or in addition to" the FDA requirement, does preemption take place.

- **Recommended Changes**

As noted in the introduction, state and local governments have undertaken significant efforts to control underage use of tobacco, through imposing excise taxes, restrictions on sales to minors, labeling and disclosure requirement and

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policies protecting citizens from secondary effects of smoking. ACS believes that as a general rule, states and localities should be authorized to enact laws that are the same as, or more stringent than, federal tobacco control laws. The following changes would implement this policy:

- 1. The "Penalties and Enforcement" provision would preempt state laws governing penalties and enforcement. These provisions appear to contradict provisions found elsewhere in the proposed settlement. Legislation should provide that state and local enforcement authority and penalties may be more stringent than federal law.*
- 2. In addition, the ACS recommends that Congress carefully review the implications of any new federal law regulating tobacco products as medical devices and clearly specify instances, such as requirements for modification of tobacco products or good manufacturing practice requirements, in which preemption is warranted. Requirements under the Federal Food, Drug and Cosmetic Act for labeling and advertising of devices should not serve as barriers to additional state and local requirements as long as they do not conflict with requirements imposed by the FDA.*
- 3. Because the Labeling Act precludes many state and local health requirements implementing the initiatives as well as many common law tort claims, the ACS recommends that the legislation include a provision amending the preemptive language of the Labeling Act. Such an amendment should permit states and localities to enact laws which enhance and supplement the goals of the Labeling Act.*

V. REDUCING UNDERAGE TOBACCO CONSUMPTION AND "LOOK BACK" PROVISIONS

- **Summary of Settlement Provisions (pp. 24-25)**

The "look-back" provision sets specific targets for the reduction of underage smoking and use of smokeless products over the next ten years. These targets are as follows:

Smoking Reduction	Smokeless Reduction	Year
30%	25%	5th
50%	35%	7th
60%	45%	10th

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If the targets are not met, the FDA may impose a mandatory surcharge on the relevant industry (i.e., cigarette or smokeless tobacco) based on the estimated profit the industry would earn over the lives of all underage users in excess of the target. The surcharge is subject to an annual cap of \$2 billion for the cigarette industry and a proportional cap for the smokeless tobacco industry.

Manufacturers are eligible to receive a partial abatement, up to 75%, of the surcharge. To receive the refund, a company must prove:

- (a) it "acted in good faith" and in full compliance with all laws;
- (b) it pursued "all reasonably available measures" to attain the targets; and
- (c) there is no evidence it took action to undermine achievement of the goals.

Additionally, states are required to have a "no sales to minors" law. Each state must conduct 250 random, unannounced inspections per one million population annually to ensure retailer compliance. The FDA must determine, on an annual basis, whether each state has "pursued all reasonably available measures" to enforce the ban on tobacco sales to minors. Further, FDA must presume that a state has not met this standard if the following compliance rate targets are not met:

Year	Retail Compliance Rate
5th	75%
7th	85%
10th	90%

States that fail to meet enforcement targets will lose Medicaid-related funds from the settlement for each percentage point it exceeds a target, up to a maximum of 20%. The FDA must refund up to 75% of the withheld funds, however, if the state shows:

- (a) it acted in good faith and full compliance with all laws;
- (b) it pursued "all reasonably available measures to attain" the targets; and
- (c) there is no evidence it took action to undermine the achievement of the goals.

• ACS Analysis and Recommended Changes

While the concept is sound, the effect of the "look back" provisions may be limited. As written, the proposal does not include sufficient economic incentive to ensure that industry will meet the targets established in the proposed settlement. However, properly crafted, "look back" provisions can provide a strong motivation for the industry to comply with other aspects of the settlement and to

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take seriously their responsibility and role in decreasing underage tobacco consumption. As they are included in the settlement proposal, however, the provisions are seriously flawed and should be amended. Proposed changes include the following:

1. Lower targets should not be allowed for smokeless tobacco products than for cigarettes or other tobacco products. Over the past 10 years, the increase in use of smokeless products among teenage boys has outpaced that of cigarettes.

Recommended Change: Raise the targets for smokeless tobacco products to the same level as cigarettes. Any legislation should include all tobacco products; i.e. cigars, pipe tobacco as a target objective.

2. There is insufficient incentive for an individual manufacturer to curb its own marketing efforts to attract potential underage users, since it will not be proportionally accountable for any violation of the targets.

Recommended Changes

- a. Remove the perverse incentive for tobacco companies to gain a disproportionate share of the underage market by imposing the surcharge on each company individually based on brand-specific youth consumption.

- b. Appropriate sales data, by brand, must be provided by the companies to allow evaluation of performance by individual companies.

3. An economic analysis of the tobacco industry by Jeffrey Harris, M.D., Ph.D., an economist at the Massachusetts Institute of Technology, indicates that the present value of the \$80 million surcharge and the \$2 billion cap are too low to serve as an effective deterrent. ^{2/} According to Dr. Harris, even under optimistic assumptions, the industry could pass along a \$2 billion surcharge to consumers by increasing prices only 8 to 10 cents per pack. The surcharge must be high enough to ensure vigorous efforts to meet statutory targets.

^{2/} See Tab 16 of the ACS Review and Analysis.

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Recommended Change: *The \$2 billion cap should be ~~eliminated~~, and surcharge payments should be at a rate to provide an effective incentive for industry to help achieve results.*

4. The rebate provision is so broadly worded that it could be interpreted to allow a rebate even if a manufacturer took only token efforts to meet targets. Moreover, the reward so high (mandatory 75% refund) that the industry has a much stronger incentive to fight for the rebate than to achieve the youth reductions, thus completely undermining the intent and effectiveness of the "look-back" provisions.

Recommended Change: *Eliminate the rebate altogether.*

5. In an effort to minimize the effectiveness of random, unannounced inspections by local authorities, the tobacco industry has succeeded in passing laws in many localities banning the use of minors as straw purchasers.

Recommended Change: *Implementing legislation should explicitly authorize state and local governments to use minors in compliance checks.*

6. The Secretary of Health and Human Services has estimated that three-fourths of the approximately one million tobacco outlets sell tobacco to minors.

Recommended Change: *With this many outlets, it is critical that any "no sales to minors" law must require the licensing authority to conduct, or to arrange for, periodic compliance checks at every licensed store. These checks should be conducted, at a minimum, two or three times annually. 2/*

VI. DISCLOSURE AND REGULATION OF NON-TOBACCO INGREDIENTS

- **Summary of Settlement Provisions (pp. 19-20)**

Under the Comprehensive Smoking Education Act ("Smoking Education Act"), each manufacturer, packer or importer of cigarettes must annually

3/ See No Sale: Youth Tobacco and Responsible Retailing: Developing Responsible Retail Sales Practices and Legislation to Reduce Illegal Tobacco Sales to Minors. Findings and Recommendations of a Working Group of State Attorneys General.

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provide the Secretary with a list of ingredients added to cigarettes during their manufacture. The list may not identify the company which uses the ingredients or the brand of cigarettes which contains them. The Secretary is to transmit to Congress a report based on such information of a summary of research activities and their findings, on the health effects of the ingredients, and information on any ingredient which, in the judgment of the Secretary poses a health risk to cigarette smokers.

The settlement proposes adoption of legislation that would supersede the reporting requirements of the Smoking Education Act and replace them as follows:

1. Manufacturers would be required to provide FDA on a confidential basis a list of non-tobacco ingredients, by brand.
2. Within 5 years of enactment of the legislation, manufacturers would be required to submit for each ingredient, a safety assessment demonstrating that "there is a reasonable certainty in the minds of competent scientists that the ingredient (up to a specified amount) is not harmful" under intended conditions of use. FDA must review the safety and approve or disapprove the use of the ingredient. If FDA takes no action within 90 days, the ingredient would be deemed approved.
3. New ingredients, or the addition of current ingredients beyond the specified amount, would be subject to comparable requirements to submit a safety assessment.
4. The settlement contemplates treatment of some ingredient information as confidential, and protects ingredient information not subject to disclosure under federal food law. For 5 years, such information would not be required to be disclosed unless FDA disproves the safety of an ingredient.

• **ACS Analysis**

Overall, the proposal for the first time would require submission of specific information on tobacco ingredients, by brand, to FDA and require a demonstration of safety of the ingredient, much like that required of a food additive.

The description of the confidentiality provisions is somewhat unclear, however, since as a general rule there is no trade secret provision under food law that protects disclosure of ingredients. Percentages of ingredients are protected, as are flavors and manufacturing processes. But the existence of an ingredient is not regarded as trade secret information.

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- **Recommended Changes**

- * 1. *"Ingredients" must include all additives and other substances derived from tobacco, as well as non-tobacco ingredients.*
- * 2. *There is no justification for denying the public access to information on the existence of ingredients in tobacco and legislation including such a provision should be rejected.*
- 3. *The legislation should specifically provide FDA with the authority and responsibility to establish safety standards to serve as the basis for the safety assessment.*
- 4. *The provision authorizing inclusion of an ingredient in tobacco if a safety assessment is not acted upon within 90 days should be deleted.*
- 5. *The legislation should make it clear that a safety assessment must include an evaluation of ingredients used in combination with each other, as well as the fact that ingredients are altered through burning.*

VII. REDUCED RISK PRODUCTS / "SAFER CIGARETTES"

- **Summary of Settlement Provisions (pp. 14-15)**

The proposed agreement would bar tobacco product manufacturers from making claims that state or imply a reduced health risk, unless it can demonstrate to the FDA that the product in fact "significantly reduces the risk to health" compared to ordinary tobacco products. Additionally, the FDA has authority to approve all health claims made in advertisements in order to "prevent the public from being misled."

With regard to tobacco products that the agreement refers to as "less hazardous," the FDA may permit scientifically-based health claims. In addition, the FDA can provide exceptions to the advertising restrictions that apply to other products if it determines that to do so would "reduce harm and promote the public health."

If a manufacturer develops or acquires technology that reduces the risk from tobacco products, it is required to notify FDA and cross license such technology for a reasonable fee to other manufacturers. Procedures to resolve license fee disputes and assurance of protection of confidential data during the development process are contemplated.

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Importantly, in any judicial review of the FDA's action, deference to the FDA's findings will depend on the extent to which the matter at issue is within the agency's field of expertise.

- **ACS Analysis**

Mandatory licensing of trade secret data has been successfully accomplished through amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in 1972 and 1978. Under current law, when pesticide research data submitted to EPA are considered by the agency in support of another company's registration, compensation of the company that first submitted the data is required. Initially, EPA hearing examiners determined what constituted "reasonable" compensation; this responsibility was transferred to private arbitrators in 1978.

FIFRA's mandatory data licensing and compensation scheme has survived a constitutional challenge as a governmental "taking" of private property without just compensation in violation of the Fifth Amendment. Ruckelshaus v. Monsanto Co. In Thomas v. Union Carbide Agricultural Products Co., the Supreme Court concluded that the delegation of adjudicatory power to arbitrators, rather than the courts, did not violate the "separation of powers" required by the Constitution.

- **Recommended Changes**

Legislation implementing this proposal must be carefully crafted to ensure that --

1. *FDA is provided the authority, and the resources, to establish an appropriate means of measuring risk, and determining reduced risk.*

2. *Approval by FDA as a "reduced risk" product must be based on both reduced risk and whether it makes a contribution to reducing addiction.*

3. *The "reduced risk" program should be balanced by efforts to facilitate, and expedite, development and approval of pharmaceutical products to treat tobacco dependence.*

AMERICAN CANCER SOCIETY**ANALYSIS OF REMAINING TERMS OF
THE PROPOSED TOBACCO SETTLEMENT****VIII. AG'S RECOMMENDED ALLOCATION OF PUBLIC HEALTH FUNDS**

- **Summary of Settlement Provisions (pp. 36-38)**

Of the \$368.5 billion in payments that will be received from the tobacco companies over twenty-five years, the Agreement recommends that approximately \$93 billion, or roughly 25% of the total payments, be used to fund public health programs, as follows:

- HHS will receive \$125 million for the first three years, and \$225 million annually thereafter to fund youth prevention, adult cessation, research and other programs.
- FDA will receive \$300 million annually to carry out its obligations and to enforce the provisions of this settlement.
- State and local governments will receive \$75 million for the first two years, \$100 million the third year, and \$125 million annually thereafter to fund community-based prevention programs.
- \$100 million per year will be dedicated to fund research and development of tobacco prevention and cessation methods.
- Sports teams and events that lose tobacco industry sponsorship will receive \$75 million per year for the first 10 years following the effective date of the settlement. After 10 years, these funds will be reallocated to other public health programs.
- An independent, non-profit organization to be formed will receive \$500 million per year to fund multi-media public education campaigns.
- A newly formed Tobacco Cessation Trust Fund will receive \$1 billion per year for the first four years and \$1.5 billion per year thereafter. The fund, which will be managed by the Secretary of HHS, will be used to assist existing smokers in their efforts to quit smoking.
- A Public Health Trust Fund under the control of a Presidential Commission will receive \$25 billion to fund specific tobacco-related medical research. Representatives from the

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public health community and state Attorneys General will serve on the Commission.

- **ACS Analysis**

Overall, these provisions appear promising, but they represent only the recommendations of the participating state Attorneys General. Ultimately, the President and Congress will be charged with deciding how to allocate these funds. The ACS is confident that the President and Congress will perform this function faithfully, holding the best interests of the national public health as its foremost objective.

Of greater concern, however, is the fact that these provisions only account for approximately 25% of the total industry payments. The settlement does not explicitly provide for the allocation of the remaining 75% of the payments. Presumably, these funds will be used to settle certain private law suits, to pay legal fees, and to compensate states for tobacco-related Medicaid costs.

- **Recommended Changes**

The ACS would prefer to have a greater percentage of the industry payments explicitly devoted to fund public health programs. Congress should conduct hearings to determine how much funding is needed for these public programs and which programs are most effective in achieving the stated public health goals.

While the ACS trusts that states will use the unallocated funds to pay for tobacco-related medical expenses and public health programs, the ACS believes that the settlement should provide greater detail regarding how the unallocated funds are to be used.

IX. NATIONAL TOBACCO CONTROL PROTOCOL AND CONSENT DECREES

- **Summary of Settlement Provisions (pp. 27-28)**

In order to insure that the settlement will benefit all states, including those that are not participating in the settlement, the industry will enter into a "national tobacco control Protocol" (the "National Protocol") that will embody certain terms of the Act. The National Protocol will be a binding contract enforceable by the federal government and all states, and it will not be subject to facial constitutional challenge.

In addition, the tobacco industry and the participating states will enter into consent decrees, that will reiterate, in identical language, the terms of the Act governing:

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1. advertising, marketing, and youth access restrictions;
2. trade associations;
3. lobbying restrictions;
4. disclosure of tobacco smoke constituents;
5. disclosure of non-tobacco ingredients;
6. disclosure of industry research "relating to health, toxicity and addiction;"
7. compliance and corporate culture;
8. payments to the states;
9. obligations to deal only with complying distributors/retailers;
10. warnings, labeling and packaging; and
11. dismissal of other pending litigation specified by the parties.

The consent decrees will not include the terms of the agreement governing:

1. product design, performance or modification
2. manufacturing standards and good manufacturing practices
3. testing and regulation of toxicity and ingredients approval; and
4. the national FDA look back provisions.

The settlement requires that the consent decrees be construed in conformance with the Act and the National Protocol, and with each other. The parties shall expressly waive all constitutional challenges to the consent decrees, and the terms of the consent decrees shall remain binding upon the parties even if corresponding provisions of the Act are declared unconstitutional.

- **ACS Analysis**

Although the content of the National Protocol is not clearly defined, this provision will serve the important function of extending the settlement to the ten non-participating states. Thus, the ACS supports this provision as a means of establishing and maintaining a nationally unified campaign to reduce tobacco use and improve public health.

The ACS also supports the Consent Decree provisions because they provide an important "back-up" system which will remain effective even if portions of the Act are declared unconstitutional. Although the parties to the settlement will not have standing to challenge its constitutionality, the Act is likely to face numerous constitutional challenges from third parties.

- **Recommended Changes**

The consent decrees must also provide for the achievement of agreed-upon public health goals as a "safety net" in case federal legislation flounders.

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Congress should also require the parties to submit draft consent decrees and a draft National Protocol in the early stages of developing federal legislation so Congress can determine whether these three pieces "fit" together, and determine how conflicts in enforcement, claimed rights, and procedures can be resolved.

X. LICENSING OF RETAILERS

- **Summary of Settlement Provisions (pp. 12-13)**

The provisions to eliminate youth access to cigarettes and smokeless tobacco are enhanced by a requirement that the Federal government establish minimum standards for a retail licensing program financed through funding provided by industry payments. The licensure program would apply to all manufacturers, distributors, wholesalers, retailers, and importers of tobacco products. It would be enforced by federal, state and local authorities. The new licensing program:

- Prohibits the sale of tobacco products to consumers by an unlicensed seller;
- Requires that applicants and holders of a license comply with all federal statutes and regulations governing tobacco products;
- Imposes licensing fees to cover costs incurred by states to administer the licensing program;
- Establishes comparable Federal licensing provisions for the military and other U.S. Government operations and for Indian tribes.

The settlement also specifies penalties for violation of the licensing laws. Any person who sells tobacco products without a license is subject to criminal sanctions, including a \$1,000 fine, six months imprisonment, or both. For corporations, the settlement calls for a maximum fine of \$50,000. States may impose more severe penalties than those set forth under federal law.

Civil sanctions for violating state licensing laws governing the sale of tobacco to minors could result in fines and license suspension or revocation, depending on the number of offenses committed within a two-year period. Each state must enact an enforcement scheme that provides "substantially similar standards" to the federal minimum. Civil penalties are as follows:

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<u>Offense w/in 2 yr. pd</u>	<u>Maximum Civil Penalty</u>
First	\$500, 3 day license suspension, or both
Second	\$1,000, 7 day suspension, or both
Third	\$2,000, 30 day suspension, or both
Fourth	\$5,000, 6 month suspension, or both
Fifth	\$10,000, one year suspension, or both
Sixth - Ninth	\$25,000 or mandatory revocation for 3 years
Tenth	Mandatory license revocation

- **ACS Analysis**

If adequately funded and administered, a national licensing system can help reduce illegal sales to minors. However, research of local enforcement schemes for both tobacco and alcohol demonstrate that license suspension and revocation are much more effective deterrents to reducing illegal sales to minors than financial penalties.

While states may impose more severe criminal penalties, the civil penalties are clearly stated and states are required to enact laws imposing similar penalties. This penalty scheme would expressly preempt more stringent and effective state and local sanctions, such as required license revocation.

The requirement that state and local governments enforce the licensure provisions would be allowed under tenth amendment analysis. In Printz v. United States and New York v. United States, the Supreme court makes clear that the federal government may not commandeer states to carry out federal objectives, despite Congress' power to pass laws under the Commerce Clause. That is, the federal government cannot impose unfunded mandates on states. However, in this case, the requirements are funded by tobacco industry payments, and therefore, the provisions requiring enforcement of licensure provisions are Constitutional.

- **Recommended Change**

Delete the option of financial penalties for second and subsequent offenses, make the escalating schedule of suspensions mandatory, and require license revocation after the third offense.

XI. NATIONAL CLEAN INDOOR AIR STANDARDS

- **Summary of Settlement Provisions (pp. 30-31)**

The proposed settlement agreement restricts indoor smoking in "public facilities" (a building entered by 10 or more people at least one day per week) to

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negatively pressurized areas ventilating directly to the outside. Employees shall not be required to enter the smoking area while smoking is occurring. Restaurants (other than "fast food restaurants"), bars, private clubs, hotel guest rooms, casinos, bingo halls, tobacco merchants and prisons are exempted. The settlement would require OSHA to issue regulations to implement and enforce these standards, with enforcement costs paid by the industry, but would become effective within one year regardless of OSHA's actions. *fine*

The act would not preempt or otherwise affect any other state or local law that impose the same or more stringent restrictions on smoking in public facilities. Similarly, the agreement does not preempt or otherwise affect any federal rules that restrict smoking in federal facilities.

- **ACS Analysis**

These provisions summarize H.R. 1771, "To Amend the Public Health Act to Protect the Public from Health Hazards Caused by Exposure to Environmental Tobacco Smoke," introduced by Representative Waxman on June 3, 1997. There is no federal preemption provision in the bill.

- **Recommended Change**

The ACS supports H.R. 1771 and recommends its adoption as part of the legislation implementing the settlement agreement. See section III on ACS recommendations regarding preemption.

XII. RESTRICTIONS ON MARKETING AND ADVERTISING

- **Summary of Settlement Provisions (pp. 8-9)**

The Settlement proposal includes the following restrictions on marketing and advertising:

- Authorize only black and white, text-only ads in publications with 15%+ youth readership;
- Ban brand-name event sponsorship, such as concerts and sports;
- Ban all billboards, outdoor signs, and signs in arenas;
- Ban all human images and cartoon characters from advertising and packaging;
- Ban advertising on non-tobacco products, like caps, jackets and bags;

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- Ban use of non-tobacco brand names on tobacco products;
 - Ban offers of non-tobacco items or gifts based on proof of purchase;
 - Require ads to carry FDA-mandated statement "Nicotine Delivery Device;"
 - Prohibit point-of-purchase ads in all facilities other than adult-only stores and tobacco outlets (with very limited exceptions);
 - Ban advertising on the Internet, unless "designed to be inaccessible in or from the [U.S.];"
 - Prohibit payments to place products in movies, TV programs and video games, or "to 'glamorize' tobacco use in media appealing to minors," including records and concerts;
 - Require disclaimer in ads with "product descriptors (e.g., 'light' or 'low tar')"; and
 - Require FDA review of all new ads and labels concurrent with introduction.
- **ACS Analysis and Recommended Changes**

Overall, ACS strongly supports all of the proposed marketing and advertising restrictions, which appear to have the potential to impact public health in a positive way. However, there are several shortcomings and weaknesses that need to be corrected.

1. In the first five years, the FDA may alter or strengthen these marketing restrictions only under "extraordinary circumstances," even though the industry may develop new, unanticipated or even unintentional marketing techniques that continue to appeal to minors.

Recommended Change: *Delete the condition that FDA can make changes only under "extraordinary circumstances".*

2. Cigars and pipes are exempt from advertising restrictions, even though cigar use among minors is climbing fast.

Recommended Change: *Apply the advertising and marketing restrictions to "all tobacco products."*

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3. The industry may continue using traditional product "descriptors" such as "light" and "mild" simply by adding a disclaimer in their ads, even though surveys show 60% of smokers wrongly believe such cigarettes are less harmful. On the other hand, a new and genuine reduced-risk product may not list such claims unless the manufacturer "demonstrates scientifically" that the product "significantly" reduces health risk.

Recommended Change: *Require traditional product "descriptors" like "light" and "mild" to meet the same health claim standards established for new, reduced-risk products.*

XIII. RESTRICTIONS ON YOUTH ACCESS TO TOBACCO

- **Summary of Settlement Agreement (pp. 11-12)**

Under the settlement agreement, FDA would be provided explicit authority to:

- Ban sales to kids under 18;
- Require photo i.d. for anyone under 27 and a face-to-face transaction;
- Ban all vending machines;
- Require minimum pack of 20;
- Ban sale of single cigarettes and free samples;
- Prohibit mail order sales except with proof of age, with FDA review after two years; and
- Ban self-service displays, except in adult-only facilities, and tobacco must be behind the counter, under lock, or if on the counter not visible or accessible.

- **ACS Analysis**

ACS strongly supports these needed measures, but recognizes that without adequate enforcement, they will be of little use. Recently, Congress cut the administration's proposed budget for enforcing the current FDA rule from \$34 million to \$15 million.

- **Recommended Change**

Insure that industry funds earmarked for enforcement may not be cut by appropriations committees.

AMERICAN CANCER SOCIETY**XIV. WARNINGS, LABELING AND PACKAGING**

- **Summary of Settlement Provisions (pp. 9-11)**

Under the settlement agreement, manufacturers of cigarette packs would be required to rotate eight explicit warnings, including "cigarettes are addictive," "cigarettes cause cancer," and "smoking can kill you" on a large label covering 25% of the upper front panel. Smokeless tobacco would carry four similar warnings. Warnings must cover 20% of all advertisements. FDA may "require label and advertising disclosures relating to 'tar' and nicotine, [and] disclosures by other means relating to other constituents."

- **ACS Analysis**

These are significant improvements over the existing warning labels. However, under the proposal:

1. Only the front of packages require warnings.
2. Industry package designers may develop new ways to minimize the impact of the warning labels.

- **Recommended Changes**

1. *Require warnings on the back of packages as well.*
2. *Require FDA to issue regulations on warning labels that prevent manufacturers from using packaging or design techniques that reduce the impact of the warnings.*

AMERICAN CANCER SOCIETY**ECONOMIC ANALYSIS OF THE
PROPOSED TOBACCO SETTLEMENT 1/**

It has been widely reported that U.S. cigarette manufacturers will be required to pay a total of \$368.5 billion during the first 25 years of the tobacco industry-wide Proposed Resolution. 2/ This characterization of the settlement payments, however, substantially overstates the real value of the amount that will actually be paid.

- The reported 24-year total of \$368.5 billion does not take into account the "adjustment for volume" provisions in the Proposed Resolution. 3/ This provision essentially pegs all payments to the volume of cigarettes sold, and therefore renders the payment scheme equivalent to a unit tax on cigarettes. As the Proposed Resolution contemplates, 4/ this virtual tax will be passed on to consumers in the form of higher prices. As a result, the volume of cigarettes sold will decline, and therefore total industry payments will decline, too.
- Based on a conservative economic model of the relation between cigarette consumption and cigarette prices, 5/ I estimate that the real price of a pack of cigarettes (in 1996 dollars) will rise by \$0.41 per pack in 1996 dollars at the outset. This virtual tax will gradually increase to \$0.62 per pack (in 1996 dollars) by the fifth settlement year, and remain at that level indefinitely.

1/ Prepared by Jeffrey E. Harris, M.D., Ph.D. of the Massachusetts Institute of Technology and Massachusetts General Hospital. The views expressed here are those of the author. They do not necessarily represent the position of the Massachusetts Institute of Technology or the Massachusetts General Hospital.

2/ "Proposed Resolution: For Settlement Discussion Purposes Only. 6/20/97, 3:00 p.m. DRAFT." 68 pp.

3/ "Proposed Resolution... Title VI, B5," at p. 34.

4/ "Proposed Resolution... Title VI, B7," at p. 35.

5/ See Harris, J.E. "Comments on: Proposed Resolution: For Settlement Discussion Purposes Only. 6/20/97, 3:00 p.m. DRAFT." 68pp." Commissioned by the American Cancer Society, June 26, 1997. My model assumes that current price elasticity of demand is -0.4, and that, even in the absence of price increases, cigarette consumption will decline at a background rate of 0.6% annually.

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- If the virtual tax is fully passed on to American smokers, as I expect it will, then total U.S. cigarette consumption will fall from 24.2 billion packs annually to 22.3 billion packs in the base year of the settlement, and continue to decline gradually to 18.4 billion packs by the 25th year. Applying the volume adjustment provision, I estimate that the face value of industry payments would amount to \$304.3 billion over 25 years. 6/
- The face value of industry payments, however, does not reflect their *present discounted value*, that is, the amount that investors would be willing to pay today for a portfolio of 25-year corporate bonds that promised to pay exactly what the Proposed Resolution mandates. Based on an interest rate comparable to the long-term rates on corporate bonds and U.S. Treasury obligations, I estimate that the *present discounted value* of volume-adjusted industry payments would be \$194.5 billion over 25 years. 7/

The Proposed Resolution imposes financial penalties on cigarette manufacturers if the proportion of 13- to 17-year-olds who smoke cigarettes every day does not reach specified target levels within 5 to 10 years. 8/ While economic research suggests that teenagers' smoking rates may be especially responsive to price, the increase in cigarette price anticipated from the Proposed Resolution would be insufficient by itself to reach the specified targets.

- Based upon my analyses of data from the University of Michigan's "Monitoring the Future" Study, I estimate that the "base percentage" of underage daily smokers (that is, the 1986-1996 historical average) is 15.2% 9/

6/ This computation does not include the drop in Federal excise tax revenues and state excise and sales tax revenues on cigarettes that would result from falling cigarette consumption. For example, even if states raised their excise and sales taxes to keep pace with inflation, the loss in state revenue would have a face value of \$43.2 billion over 25 years.

7/ My calculations of present discounted value took into account the "inflation protection" provision (Tile VI, B.4) of the Proposed Resolution.

8/ See Appendix V of the Proposed Resolution.

9/ See "Monitoring the Future" Study. *Cigarette Statistics Table I: Long-Term Trends in Prevalence of Cigarettes for Eighth, Tenth, and Twelfth Graders*. Ann Arbor: Univ. Michigan, 1997. I estimate the base percentages to be: 8.5% for 8th graders; 14.7% for 10th graders; and 19.2% for 12th graders. The population-weighted average, as specified in Appendix V, A.1 of the Proposed Resolution, would then be 15.2%.

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Hence, the five-year goal of a 30% reduction in underage smoking prevalence would mean a target rate of 10.6% daily smokers. This target actually amounts to a 58% reduction from the current 1996 prevalence of 18.2% among eighth- to twelfth-graders. 10/

- Based upon the most recent economic research on the responsiveness of youth smoking to increases in cigarette prices, 11/ I estimate that the expected \$0.62 increase in the real price of cigarettes would translate into an 18% reduction in teenage smoking from its 1996 level, that is, to about 14.9% daily smokers, which is well above the calculated target rate of 10.6% daily smokers. 12/

I compared the effect of the Proposed Resolution on cigarette consumption and governmental revenues with that of an inflation-adjustable increase in the Federal excise tax on cigarettes. A \$1.00-per-pack tax, levied by Congress in the base year and adjusted to keep pace with inflation, would yield approximately 60% more revenues over 25 years than the Proposed Resolution. An inflation-adjusted \$1.50-per-pack tax would yield more than twice the revenues expected from the Proposed Resolution. A \$1.50-per-pack price increase, I estimate, would be sufficient by itself to reduce the 13- to 17-year-old daily smoking rate to the target level contemplated by the Proposed Resolution.

10/ The 1996 rates of daily smoking in the "Monitoring the Future" Study were: 10.4% for 8th graders; 18.3% for 10th graders; and 22.2% for 12th graders. The population-weighted average, as specified in Appendix V, A.1, would then be 18.2% for 1996.

11/ See Chaloupka FJ, Grossman M. "Price, Tobacco Control Policies and Youth Smoking," Working Paper No. 5740. Cambridge MA: National Bureau of Economic Research, Sept. 1996. These authors estimated the "participation price elasticity," which captures the effect of price on the proportion of youth who smoke, to be -0.6. The "overall price elasticity," which also includes the effect of price on the number of cigarettes that youth smokers consume, was estimated to be -1.3.

12/ Under the surcharge provisions of Appendix V, the resulting smoking prevalence would amount to only a 2% reduction from the "base percentage" of 15.2%. Hence, the reduction in underage smoking rates would fall 28 percentage points below the 30-percent target. While provisions B.1(b)(1)-(3) of Appendix V (pp. 53-54) are complex, it appears that the resulting surcharge would reach the \$2 billion cap imposed by provision B.1(b)(4)(p.54). If this surcharge were passed onto all consumers in the form of higher retail prices, the effect would be about \$0.08 per pack.

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- If Congress raised the cigarette excise tax by \$1.00 per pack and periodically revised the tax to keep pace with inflation, then the face value of industry payments would be \$480.1 billion over 25 years, as compared to \$304.8 billion under the Proposed Resolution. The present discounted value would be \$314.4 billion, as compared to \$194.5 billion under the Proposed Resolution. By year 24, total U.S. cigarette consumption would be 17.1 billion packs, as compared to 18.4 billion under the Proposed Resolution. The daily smoking rate among 13- to 17-year-olds would decline to 12.9%, as compared to the 14.9% rate expected under the Proposed Resolution. 13/
- If Congress raised the cigarette excise tax by \$1.50 per pack and periodically revised the tax to keep pace with inflation, then the face value of industry payments would be \$653.2 billion over 25 years, as compared to \$304.3 billion under the Proposed Resolution. The present discounted value would be \$427.8 billion, as compared to \$194.5 billion under the Proposed Resolution. By year 25, total U.S. cigarette consumption would be 15.5 billion packs, as compared to 18.4 billion under the Proposed Resolution. 14/ Thus, an inflation-adjustable tax of \$1.50 per pack would, by itself, result in a decline in youth smoking sufficient to achieve the target rate of 10.9% contemplated by the Proposed Resolution.

13/ Since cigarette consumption would decline, there would be a reduction in state excise and sales tax receipts equal to \$59.6 billion in face value and \$37.0 billion in present discounted value over 25 years. See footnote 6.

14/ Since cigarette consumption would decline, there would be a reduction in state excise and sales tax receipts equal to \$77.5 billion in face value and \$48.7 billion in present discounted value over 25 years. See footnote 6.