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The Inquirer National
Thursday, July 31, 1997

Tobacco pact splits two health leaders

A former AMA chief strongly endorsed the deal. The CEO of the American Cancer Society was less impressed.

By Dick Polman
INQUIRER STAFF WRITER

WASHINGTON -- Two prominent public-health leaders differed sharply yesterday on whether the proposed national settlement with the tobacco industry would save America's children or sell them out.

In congressional testimony, Lonnie Bristow, who as president of the American Medical Association participated in the settlement talks, declared that this deal ``has public-health opportunities which would potentially dwarf the impact of even the polio vaccine."

But John Seffrin, chief executive officer of the American Cancer Society -- which was not party to the talks -- told the Senate Judiciary Committee that ``this is not the right settlement" and that the deal contained ``substantial" flaws.

Seffrin said that the deal -- negotiated primarily by the tobacco industry, state attorneys general, and a children's health lobbyist -- was filled with fine print that would ``complicate and encumber" the Food and Drug Administration's embryonic attempts to police tobacco and reduce nicotine levels. Unless the FDA is freed of these restrictions, Seffrin said, the deal should be rejected.

But Bristow insisted that this pact ``represents the best that everyone could come away with" and was not a sweetheart deal for Big Tobacco.

`Acrimony and distrust'

Although Bristow wasn't officially testifying for the AMA -- he stepped down as president last month -- members of the public-health community spoke privately yesterday of ``acrimony and distrust" within their ranks. The AMA is expected to announce its official position today.

Under terms of the deal, which must be ratified by Congress and the White House, 40 states suing to recover health-care costs would end their suits in return for $368 billion from the tobacco industry over 25 years. The firms would accept broad curbs on ads and marketing while agreeing to finance tobacco education and pay penalties if youth smoking isn't reduced -- all in return for broad immunity from lawsuits and an annual cap on damage payments. The American Cancer Society has opted to join the deal's critics, whose ranks include former Surgeon General C. Everett Koop and former FDA Commissioner David A. Kessler.

Few harsh words

Mississippi Attorney General Mike Moore, the prime mover for the deal, insisted during a break that the cancer society was essentially on his side: ``I only deal with John Seffrin, and he came out pretty

strongly for [me] today." Indeed, Seffrin had few harsh words in his testimony; however, his written submission closely tracked the objections raised by Koop and Kessler, and by, among others, the American Lung Association.

Seffrin said that the pact wouldn't adequately punish Big Tobacco if it failed to reduce youth smoking by 60 percent over the next 10 years -- as promised. The industrywide penalty would be capped at $2 billion a year, which, he said could be merely passed along to consumers by increasing the price of a pack of cigarettes by a dime.

Also, he said, ``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. The documents are believed to contain incriminating evidence on marketing research, strategies to induce teenagers to use tobacco, studies on health dangers, and political strategies." Bristow, however, said that the deal would allow a three-judge panel to review secret company documents and rule on whether they should be unsealed.

Moore, the Mississippi attorney general, said later: ``This settlement is like a rubber band. You can stretch it only so far before it breaks and the industry walks away."
The deal's defenders want congressional ratification before the end of the year, when state lawsuits against the industry come to trial, starting with Florida and Minnesota. Quick passage of the deal as negotiated is unlikely, but Sen. Orrin G. Hatch of Utah, the Republican chairman of Judiciary, said yesterday: ``If we can work out a balanced budget with President Clinton, then surely we can work this out too."

Thursday July 24 3:16 PM EDT

Company Press Release

Source: American Cancer Society

American Cancer Society Releases Position on Proposed Tobacco Settlement

WASHINGTON, July 24 /PRNewswire/ -- The American Cancer Society (ACS) today released its position on the proposed tobacco settlement between the 40 states' Attorneys General and the tobacco industry at a press conference in Washington DC. The ACS recommended changes to seven issue areas which would significantly strengthen the proposed tobacco settlement in order to achieve the public health goals set forth by the Attorneys General when they began their discussions.

``The American Cancer Society supports the right settlement -- but this is not that settlement," said ACS Chairman George Dessart. ``While we believe the comprehensive legislation which will result from the settlement discussions has more potential for advancing public health than the uncertain outcome of lengthy continued litigation or piecemeal legislation, we do have concerns. There are major elements of the current settlement proposal that will require substantial revisions for the agreement to succeed in its more important potential benefit to public health -- reducing tobacco use and therefore tobacco-caused disease and death."

``The ACS is committed to reducing cancer deaths due to tobacco use," said John Seffrin, chief executive officer. ``We believe the proposed settlement provides a rare opportunity to make substantial inroads in combating tobacco related illnesses -- the largest cause of death and disease in the United States."

When the settlement proposal was released, ACS began a three stage comprehensive review and analysis process of the settlement document which included a review by staff and volunteer executive leadership, a specially convened panel of outside legal, economic and health policy experts, and participation in the evaluation process by Advisory Committee on Tobacco Policy and Public Health, which was chaired by former FDA commissioner David Kessler and former Surgeon General C. Everett Koop, and appointed by select members of Congress. Dr. Seffrin chaired the panel on FDA regulation of tobacco products for the Koop/Kessler committee.

Areas the ACS thinks need revision include:

Industry Payments

The amount of the required industry payments may be too small to produce significant reductions in youth smoking. The present discounted value of the required $368.5 billion payments is actually only $194.5 billion. The payments would produce a 41 cents per pack increase in the price of cigarettes in

$194.5 billion. The payments would produce a 41 cents per pack increase in the price of cigarettes in Year 1, and eventually grow to 62 cents per pack by Year 5. No other public health strategy would exhibit the speed and cost-effectiveness of impact achieved by increasing the price of tobacco products. ACS proposes:

- Raise the federal tobacco excise tax to $2 per pack of cigarettes with a proportional increase on smokeless tobacco products.
- FDA Regulation of Nicotine and Other Tobacco Constituents
- The procedural hurdles are wholly unjustified. The ACS recommends:
- Authorize FDA to develop performance standards designed to reduce or

eliminate any constituent, including nicotine;

- Delete 12 year provision and apply a single standard that applies from the effective date of the Act;
- Eliminate proposed heightened standard of proof and allow traditional administrative law to apply;
- Delete requirements that FDA demonstrate that modifications in tobacco products will not result in significant contraband; and
- Include regulation of cigars and pipe tobacco.

Preemption

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 requirements and policies protecting citizens from secondhand smoke.

*ACS believes states and localities should be authorized to enact laws that are more stringent than federal tobacco control laws.

Public Disclosure of Industry Documents

It is clear that the tobacco industry did not disclose what it knew about the dangers and addictive properties of cigarettes. ACS recommends:

*The industry be required to release to the FDA any and all information -- including research and marketing documents -- that are relevant to public health, safety, and the development of less hazardous tobacco products.

Reducing Underage Tobacco Consumption and ``Look Back" Provisions

There is no economic incentive to ensure the industry will meet the targets. The ACS recommends:

- Raise the targets for smokeless tobacco to same level as cigarettes;
- Impose a surcharge on each tobacco company based on brand-specific youth consumption;
- Eliminate the rebate provision to avoid undermining the intent and effectiveness of the ``look-back" provision;
- Add language to explicitly authorize state and local governments to use minors in compliance checks;
- Require sales data, by brand, in order to evaluate performance by individual companies; and
- Eliminate the $2 billion cap.

Disclosure and Regulation of Non-Tobacco Ingredients & Reduced Risk Products

We embrace the requirement that manufacturers be required to provide FDA a list of non-tobacco ingredients; however, ACS recommends:

- ``Ingredients" must include all additives and other substances derived from tobacco, as well as non-tobacco ingredients;
- Legislation should specifically provide FDA with the authority and responsibility to establish safety standards to serve as the basis for the safety assessment; and
- Legislation should make 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.
- The FDA be provided the authority, and the resources, to establish an appropriate means of measuring risk, and determining reduced risk in development and approval of a ``reduced risk" (safer cigarette) product.

ACS released the results of nationwide polling that looked at public support for the tobacco settlement. Polling was performed by The Mellman Group in June. Seven of the questions included:

- 69% support FDA Regulation of tobacco products;
- 84% favor disclosure of tobacco industry documents;
- 68% favor state and local ability to enact tougher laws;
- 89% support fines and license revocation for those who sell to kids;
- 78% favor licensing requirements of retailers;
- 76% support a ban on vending machines.

``Smoking is a pediatric disease and 3,000 young people begin smoking every day," said ACS President Myles Cunningham, M.D. ``We must combat this problem from all sides, because tobacco is not a partisan issue. ACS will work with Congress and the public health community to ensure that a carefully crafted piece of legislation gets developed that will end the tobacco epidemic."

The 200+ page document, which was delivered to Congress, includes a thorough evaluation of the original FDA rule, information on the regulation of nicotine as a drug, facts on the health aspects of smoking and state specific tobacco and health issues. The press conference today released the Society's official position and the organization's recommendations for developing legislation to achieve the goals of truly comprehensive national tobacco policy drive by the public health agenda. And in a few days the Society will release a complete analysis of the legal and constitutional ramifications of the settlement.

``As the settlement proposal goes through Congress, the American Cancer Society will monitor the process closely, and will work actively with our partners in the public health community to ensure the elements affecting public health are sustained and supported, and the tobacco industry is controlled," said Seffrin. ``Today, I call on my friends in the public health community, many of whom I worked with on the Koop/Kessler Committee, to join the American Cancer Society, as we monitor the progress of the tobacco settlement as it moves through Congress."

SOURCE: American Cancer Society
Contact: Jeanne Lambert, 813-253-0541, ext. 436, or Sheila Buchert, 813-253-0541, ext. 442, both of the American Cancer Society

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MEMORANDUM

July 10, 1997

TO: American Cancer Society

FROM: Stephan E. Lawton

This memorandum summarizes and offers an initial evaluation of the provisions of the proposed settlement with the tobacco companies as it applies to the regulation of nicotine. We conclude that the proposed enactment of legislation explicitly recognizing FDA's authority to regulate tobacco products represents a major advantage to the public. There are, however, unwise barriers to FDA regulation of nicotine included in the proposed settlement.

We recommend that the American Cancer Society seek five changes or clarifications to the agreement. They are as follows:

- The document apparently contemplates that the type of administrative proceeding to be conducted by FDA in developing the Performance Standards for tobacco products during the first twelve years following the enactment of the proposed legislation would involve a hearing on the record -- a protracted trial-type proceeding -- which would give tobacco companies the ability to delay the imposition of standards. The legislation should instead specify that the standards be developed after notice and opportunity for comment, pursuant to 5 U.S.C. § 553.

- It would be preferable for the legislation to be silent on the standard to be applied by a court reviewing any FDA regulation during the initial twelve year period. As noted below, requiring review under a "substantial evidence" standard could pose some difficulties for FDA.

- Requiring that FDA demonstrate that any modification in tobacco products (including the reduction of nicotine yields) must be based, inter alia, on a finding that the modification will not result in significant demand for contraband is unreasonable.

- The basis by which FDA could require elimination of nicotine from tobacco products -- preponderance of the evidence -- poses a significant barrier to effective FDA action.

- Acknowledging that Congress has the right to review and block any proposed FDA action before it becomes applicable raises concerns. Encouraging such review by Congress invites an unnecessary "second bite at the apple" on Capitol Hill by opponents of Performance Standards.

THE FDA RULE

Background

On August 28, 1996, the Food and Drug Administration ("FDA") issued final regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents. See 61 Fed. Reg. 44,396-45,318 (1996). The regulations prohibit the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18; require manufacturers, distributors, and retailers to comply with certain conditions regarding the sale and distribution of these products; require retailers to verify a purchaser's age by photographic identification; prohibit all free samples; prohibit the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time; limit the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format; prohibit the sale or distribution of brand-identified promotional non-tobacco items such as hats and tee shirts; prohibit sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permit such sponsorship in a corporate name; and require manufacturers to provide intended use information (i.e., "Nicotine-Delivery Device for Persons 18 or Older") on all cigarette and smokeless tobacco product labels and in cigarette advertising.

Jurisdiction

FDA asserted jurisdiction over cigarettes and smokeless tobacco under the drug and medical device provisions of the Federal Food, Drug, and Cosmetic Act (FDC Act). Specifically, FDA concluded that cigarettes and smokeless tobacco are

"combination products" consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body. Id. at 44,628. A United States District Court has affirmed that FDA has the authority to regulate tobacco products as medical devices and to impose access restrictions and labeling requirements on tobacco products. The court found, however, that FDA lacks authority under the FDC Act to restrict the advertising and promotion of tobacco products. The court also ordered FDA not to implement any of the agency's regulatory requirements, other than those prohibiting the sale of tobacco products to minors, pending further orders by the court. 1/

Regulatory Requirements

FDA intends to regulate cigarettes and smokeless tobacco products under the device authorities of the FDC Act. For example, manufacturers will be required to: 1) submit medical device reports for serious adverse reactions that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing procedure; 2) register their establishment and submit device listing information; and 3) comply with the applicable device good manufacturing practice ("GMP") requirements. FDA's current regulations, however, would not control the development or manufacturing of tobacco products or impose any limitations on the nicotine content of these products.

PROPOSED RESOLUTION APPLICABLE TO REGULATION OF NICOTINE

A 64-page Proposed Resolution would resolve lawsuits brought by 40 states against the tobacco industry through enactment of legislation that, among other things, would confirm FDA's authority over tobacco products and advertising of such products. Unlike FDA's regulations, the proposed legislation would for the first time authorize the agency to regulate the development and manufacturing of cigarettes and smokeless tobacco products and the ingredients used in these products. In addition, the legislation would authorize FDA to take steps to ensure that the tobacco industry works to develop and introduce less hazardous tobacco products and to regulate the levels of nicotine in tobacco products.

Under this regulatory regime, the FDA's authority to regulate tobacco products "will be explicitly recognized and tobacco products will be classified as a

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1/ Coyne Beahm, Inc. v. FDA, 958 F. Supp 1060 (M.D.N.C. 1997).

new subcategory of a Class II device." 2/ The Class II classification would permit FDA to require modification of tobacco products, including the regulation of nicotine content, as well as permit the regulation of the sale of tobacco products to adults in accordance with Performance Standards.

Under the proposal, these Performance Standards may "require the modification of tobacco products to reduce the harm caused by those products (including the components that produce drug dependence), provided that the standard shall not require the prohibition on the sale to adults of traditional tobacco products." During the first twelve years following the effective date of the legislation, FDA may adopt Performance Standards that "require the modification of existing tobacco products, including the gradual reduction, but not the elimination, of nicotine yields, and the possible elimination of other constituents or other harmful components of the tobacco product." The Performance Standards must be based upon a finding that the modification:

- will result in a significant reduction of the health risks associated with such products to consumers thereof,
- is technologically feasible, and
- will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard.

Any such modification must be based upon a "showing of 'substantial evidence,' based upon an administrative record developed through a formal rule making subject to the Administrative Procedure[ ] Act ('APA'), with the right of judicial review." Such a modification would also be subject to the "Regulatory Reform Act of 1996 to provide time and a process for Congress to intervene should it so choose."

After the initial twelve year period, FDA may set product safety standards that go beyond the standards established previously, including the elimination of nicotine and other constituents or other demonstrated harmful components of the tobacco product. These additional modifications must be based upon the same findings listed above. Any modification that would eliminate nicotine or have an effect comparable to the elimination of nicotine must be based upon a "preponderance of the evidence" pursuant to, "at a manufacturer's election, a Part 12 hearing, or notice and comment rule making, with a right of judicial

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2/ The medical device provisions of the FDC Act authorize classification of devices into one of three classes. Devices classified into Class II -- Special Controls -- may be required to meet Performance Standards.

review." 3/ Any such action must be phased-in over a span of at least two years and would be subject to Congressional review under the "Regulatory Reform Act of 1996."

Under the proposed settlement, FDA may also regulate all direct or implied health claims regarding tobacco products. FDA may also require manufacturers either to introduce "less hazardous tobacco products" that are technologically feasible or to license such technology at a commercially reasonable rate. Any such action would take place "after a formal rule making subject to the Administrative Procedure[ ] Act, with the right of judicial review."

ANALYSIS

Benefits of the Proposed Settlement

One of the primary benefits of the proposed settlement is that the FDA's authority to regulate tobacco products as restricted medical devices "will be explicitly recognized." The proposed settlement clearly suggests that FDA's authority to regulate tobacco will be embodied in legislation. 4/

Statutory recognition of the FDA's authority to regulate tobacco would strengthen one of the major potential weaknesses in the campaign to regulate tobacco products. The Coyne Beahm decision is, of course, the principal authority supporting the FDA's jurisdiction to regulate tobacco. It carefully reviews and discards industry arguments that, with limited exceptions, FDA has no authority to regulate tobacco products as drugs or devices. It is dangerous, however, to place too great a reliance on Coyne Beahm -- like any District Court decision, it remains

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3/ A Part 12 hearing refers to a formal evidentiary public hearing under FDA regulations found at Code of Federal Regulations, Title 21, Part 12. Such hearings involve written and oral presentations, opportunity for cross-examination, submission of briefs and other trial-type procedures.

4/ Part E of the proposed settlement begins by stating that "[t]his legislation, for the first time would impose a regulatory regime to govern the development and manufacturing" of tobacco products, and then goes on to list "[e]lements of the regulatory regime" that would be included. The reference to a "regulatory regime" imposed by "legislation" probably indicates that, under the proposed settlement, Congress will go beyond mere silent acquiescence in FDA's assertion that it has the authority to regulate tobacco products and will explicitly recognize FDA's authority to do so in a statute. ACS should confirm that Congress will affirmatively embody such authority in a statute before it agrees to support the proposed settlement.

subject to reversal on appeal and has no binding authority on any other court. Indeed, even the Fourth Circuit's decision on appeal will not foreclose similar challenges being brought in other Circuits.

In reviewing the FDA's assertion that the FDC Act granted it the authority to regulate tobacco the Coyne Beahm court applied the deferential standard laid out in Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), in which the Supreme Court held that so long as Congress has not spoken directly to the precise question at issue, courts should defer to reasonable agency interpretations of statutes. The Coyne Beahm court concluded that Congress had not expressed any clear intent with regard to FDA's authority to regulate tobacco products. Therefore, the court deferred to FDA's construction of the FDC Act asserting such regulatory authority.

The reasoning of the Coyne Beahm case indicates that its conclusion would potentially be in jeopardy as soon as an Administration were elected that was less sympathetic to FDA regulation of tobacco. Since, under the reasoning of Coyne Beahm, Congress has not clearly expressed any clear intent on the issue, courts would be obligated to defer to any reasonable interpretation advanced by FDA, even if that interpretation represented a reversal of current policy. 5/ Thus, should a subsequent FDA Commissioner interpret the scope of FDA's authority under the FDC Act differently than the current Administration has and conclude that the FDA does not possess the authority to regulate tobacco under current law, under the reasoning of Coyne Beahm a reviewing court would defer to that interpretation and hold that the FDA lacks such authority. The enactment of legislation clearly granting to FDA the authority to regulate tobacco products would eliminate this concern.

POTENTIAL PROBLEMS WITH THE PROPOSED SETTLEMENT

1. The Requirement of Formal Rulemaking Procedures

Under the proposed settlement, FDA would have the authority to adopt Performance Standards and mandate the introduction of "less hazardous tobacco products" only after a "formal rule making" subject to the Administrative Procedure Act ("APA"). Under the APA, in order to promulgate a rule, in most cases

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5/ As the Coyne Beahm court explicitly recognized, under Supreme Court precedent agencies are allowed to alter their interpretations of the statutes they administer. 958 F. Supp. at 1070 (slip op. at 17-18) (citing Chevron, 467 U.S. at 863-884; Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983); and Rust v. Sullivan, 500 U.S. 173 (1991)).

agencies are required to publish a notice of proposed rule making in the Federal Register, permit interested persons to submit comments, and to incorporate in the rules a concise statement of the rule's basis and purpose. 5 U.S.C. § 553(b)-(c). When the rules are required by statute to be made on the record after opportunity for an agency hearing, however, more extensive procedural protections apply. Id. § 553(c). The proponent of the rule has the burden of proof. Id. § 556(d). The parties are entitled to present their case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct cross examination. Id. Before any decision is rendered, parties are entitled to a reasonable opportunity to submit proposed findings and conclusions or exceptions to decisions or recommended decisions issued by subordinate agency officials, along with supporting reasons. Id. § 557(c). Thus the requirement of a "formal rule making" has the potential of enabling the tobacco companies to complicate and encumber the administrative process.

Use of the formal hearing process to develop rules has been widely criticized in administrative law circles as unnecessarily cumbersome and time consuming. Indeed, twenty-five years ago the Administrative Conference of the United States recommended that

> in future grants of rulemaking authority to administrative agencies, Congress ordinarily should not impose mandatory procedural requirements other than those required by 5 U.S.C. § 553 . . . . Congress should never require trial-type procedures for resolving questions of policy or of broad or general fact. 6/

Two FDA rulemaking proceedings involving formal hearings illustrate the basis for the recommendation of the Administrative Conference. A hearing on Foods for Special Dietary Uses consumed over 200 days of testimony and a transcript of over 32,000 pages. A proceeding to establish the standard of identity for peanut butter (largely involving the issue of whether the product should consist of 90 percent peanuts or 87 1/2 percent peanuts) developed a transcript of over 7,700 pages. In both instances, more than ten years elapsed between the first proposal and the final order. 7/

6/ Administrative Conference of the U.S., Recommendation 72-5, Procedures for Adoption of Rules of General Applicability (Adopted Dec. 14, 1972).

7/ See, generally, Hamilton, Robert W., Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking, California Law Review, Vol. 60 (Spring, 1972).

The proposed settlement appears to contemplate that Performance Standards for tobacco products may be adopted during the initial twelve-year period only after a trial type hearing and other procedures. 8/ ACS should insist on the traditional "notice and comment" rulemaking in these situations.

2. The Application of the "Preponderance of the Evidence" Test After the First Twelve Years

After the initial twelve-year period, FDA will be permitted to require the limitation of nicotine based upon a " 'preponderance of the evidence' pursuant to, at a manufacturer's election, a Part 12 hearing, 9/ or notice and comment rulemaking." 10/ This provision is problematic. Requiring that an agency base an action upon the preponderance of the evidence is extremely unusual and runs contrary to the tenets of agency expertise and accountability that underlie most of administrative law. The extent to which courts would accord deference to an agency's policy judgments under preponderance of the evidence review is simply unclear.

Furthermore, in referring to "a manufacturer's election," the proposed settlement appears to give every single tobacco manufacturer the ability to dictate the type of procedures that must be followed before nicotine can be eliminated. It is unclear how any conflicts between the different manufacturers would be resolved.

We thus strongly recommend elimination of the preponderance of the evidence test as inappropriate in the context of administrative law. Moreover, authorizing manufacturers to select the type of administrative procedure should be eliminated.

8/ The Supreme Court has restricted the applicability of procedural requirements of 5 U.S.C. §§ 556-557 to situations in which the statute clearly indicates that the rule must be made "on the record after opportunity for an agency hearing." The use of similar, less stringent language in a statute is not sufficient. United States v. Florida E. Coast Ry., 410 U.S. 224 (1973). Thus unless the legislation states on its face that rule must be made "on the record after opportunity for a agency hearing," it is unclear whether agencies are obligated to follow the §§ 556-557 procedures.

9/ See Footnote 3.

10/ It should be noted that the preponderance of the evidence standard appears to apply only to FDA action to eliminate nicotine. It would not apply to FDA efforts to restrict nicotine unless that restriction would have an effect comparable to the elimination of nicotine.

3. The "Negative" Finding with Respect to Contraband

It should not prove difficult to establish two of the factual bases required for FDA regulation of tobacco products. There is significant scientific evidence that modifications of existing tobacco products "will result in a significant reduction of the health risks associated with such products to consumers thereof," and there can be little doubt that potential modifications exist that are "technologically feasible." The other finding -- that the modification "will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard -- could be more difficult to establish. Factual data needed to establish that regulating tobacco products will not create a significant demand for contraband tobacco products may not exist at the time of rulemaking. Indeed, the provision can appropriately be characterized as requiring "proof of the negative." It would be far preferable if the statute were clarified or deleted requirements concerning demand for contraband products altogether.

4. The Application of the "Substantial Evidence" Test During the First Twelve Years

The proposed settlement specifies that the FDA may impose Performance Standards that require the modification of existing tobacco products upon a showing of "substantial evidence." This means that a reviewing court would uphold an agency's action if it were supported by substantial evidence. In the absence of a hearing or special statutory provision, a court would overturn agency action if it was "arbitrary or capricious." 11/

On its face, the substantial evidence standard appears to be somewhat more stringent than the arbitrary or capricious standard. Under the case law, however, the proposed use of the substantial evidence standard poses few concerns. The substantial evidence standard has been held to require great deference to an expert agency. As the Supreme Court has held, the evidence needed to constitute substantial evidence need only be "enough to justify if the trial were to a jury a refusal to direct a verdict." Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-490 (1951) (citing NLRB v. Colombian Enameling & Stamping Co., 306 U.S. 292, 300 (1939)); see also Illinois Central R.R. v. Norfolk & Western Ry., 385 U.S. 57, 66 (1966). 12/

11/ The APA requires that courts set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

12/ Although the substantial evidence standard is more restrictive than the extremely deferential standard that governs review of jury verdicts, it is only

Furthermore, courts have interpreted these two standards as being largely the same. Indeed, with regard to factual determinations, courts have concluded that under "the emerging consensus of the Courts of Appeals" the difference between the substantial evidence test and the arbitrary or capricious test was "largely semantic" and held that there is "no substantive difference" between the substantial evidence test and the arbitrary or capricious standard. Association of Data Processing Serv. Orgs. v. Board of Governors, 745 F.2d 677, 683-684 (D.C. Cir. 1984) (Scalia, J.) (citing cases). Thus, the "quantum of factual support . . . demanded by the substantial evidence provision of the APA . . . is . . . no different from that demanded by the arbitrary or capricious standard." Id. at 686. Moreover, courts have drawn similar conclusions with regards to policy determinations, recognizing that to the extent that agency's decisions "depend to a greater extent upon policy judgments and less upon purely factual analysis," those decisions "are not susceptible to the same type of verification or regulation by reference to the record as are some factual questions." Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 474-475 (D.C. Cir. 1974). Accordingly, even when the governing statute purports to subject policy decisions to substantial evidence review, courts review such decisions under the arbitrary or capricious standard. Id. at 476. Thus the use of the substantial evidence standard should not appreciably affect the manner in which an agency makes factual or policy determinations.

We assume that the draftsperson included a requirement for use of the substantial evidence standard because it is the standard for review when an agency hearing is required. Our recommendation for notice and comment rulemaking is, therefore, inconsistent with imposition of the substantial evidence standard and we recommend its deletion.

5. The Applicability of the "Regulatory Reform Act of 1996"

The settlement provides that any rule governing the modification of Performance Standards during the initial twelve-year period or the elimination of nicotine after the initial twelve year period would be subject to Congressional review under the "Regulatory Reform Act of 1996." This language presumably refers to Section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, which was enacted as part of the Contract with America Advancement Act of 1996, Pub. L. No. 104-121. Under this provision, Congress has sixty days to pass a joint resolution of disapproval of any "major rule" proposed by an agency. "Major

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marginally more restrictive. As the Supreme Court held, "'(s)ubstantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" Universal Camera, 340 U.S. at 477 (citing Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)).

rule" includes any rule that the Office of Management and Budget finds has resulted in or is likely to result in an annual effect on the economy of $100 million or more. It is certainly likely that Performance Standards requiring reduction in nicotine yields would have this effect on the economy. We thus question the basis for specifically authorizing Congressional Review. This provision should be deleted.

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

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.

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.

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.

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.

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.*

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

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.

- **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.

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

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

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

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.

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

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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.

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.

- **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.

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.

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

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:

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.

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:

Offense w/in 2 yr. pd	Maximum Civil Penalty
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

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.

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;

- 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."*

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.

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.

- 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%.

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 mounts 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.

- 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.