American Medical Association

Physicians dedicated to the health of America

Margaret Danaher Garikes
Assistant Director
Division of Federal Affairs

1101 Vermont Avenue, NW
Washington, DC 20005
202 789-7409
202 789-7485 Fax

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News Release

FOR IMMEDIATE RELEASE July 11, 1997

Statement is attributable to: Randolph Smoak, M.D.
Vice Chair
American Medical Association

AMA TASK FORCE BEGINS EVALUATION OF PROPOSED TOBACCO SETTLEMENT PROPOSAL

Association plans to have final word on the settlement in 30 days

In Chicago today, the American Medical Association's special task force to examine and evaluate the proposed settlement with the tobacco industry began work.

"This evaluation process constitutes the critical next step in this process. We feel a tremendous sense of responsibility to our patients and colleagues in the public health community to ensure that this settlement is the most aggressive and powerful agreement possible to protect our children and the public's health. This agreement will have implications for decades to come.

"The 12-member AMA task force, which was appointed from our House of Delegates, will meet three times over the next 30 days to thoroughly review all aspects of the proposal and will develop a comprehensive set of recommendations to assist the AMA Board in formulating a definitive position on the settlement.

"Our systematic review will ensure that the proposal meets seven criteria, which include: no legal immunity from product liability; full disclosure of the industry's documents and research regarding nicotine and the harmful effects of tobacco use; payments that are commensurate with the past and continuing harm done by tobacco; acceptance of the Food and Drug Administration regulation of nicotine as a drug; restrictions that guarantee

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Washington, DC 20005
202 789-7400

the tobacco industry will not market its products to children; no preemption of state and local laws, and; a tobacco industry-funded tobacco use prevention and education campaign. We will also be considering other key areas such as the smoking-reduction look back provision and international implications.

This task force represents a cross section of American medicine, including state and specialty societies, resident physicians, medical students and young physicians, as well as the AMA's Councils on legislation and scientific affairs. To assist in the process, the AMA has also commissioned outside experts, including former chairman of the Federal Communications Commission, Newton Minow."

# # #

For further information, contact: Brenda L. Craine
AMA Washington Office
202/789-7447

TASK FORCE ON PROPOSED TOBACCO SETTLEMENT AGREEMENT

Chair, George W. Anstadt, MD (Occupational Medicine)
Rochester, NY

Randolph D. Smoak, MD (BOT)
Orangeburg, SC

Edward J. Hill, MD (BOT)
Tupelo, MS

Ronald M. Davis, MD (CSA)
East Lansing, MI

D. Robert McCaffree, MD
American College of Chest Physicians
Oklahoma City, OK

John Slade, MD
(American Society of Addiction Medicine and international expert on nicotine addiction)
New Jersey

Ron Levine, MD
(State Health Director of North Carolina, represents the
Association of State and Territorial Health Officers in the House)
North Carolina

David R. Holley, MD (COL)
Monterey, CA

Michael J. Achinger, MD (RPS)
San Antonio, TX

Michael W. Bigelow, MD (MSS)
Milwaukee, WI

Patrick Harr, MD
President, American Academy of Family Physicians
Maryville, MO

David Callender, MD (YPS)
Houston, TX

American Medical Association
Task Force on Proposed Tobacco Settlement Agreement

George W. Anstadt, MD
Task Force Chair
Dr. Anstadt is the medical director for Kodak in Rochester, NY, and an alternate delegate to the AMA House of Delegates from the American College of Occupational and Environmental Medicine.

Randolph D. Smoak, MD
Dr. Smoak is a surgeon from Organgeburg, SC, and vice chair of the AMA's Board of Trustees. He is also an AMA representative to the Koop/Kessler Committee on Tobacco Control.

Edward J. Hill, MD
Dr. Hill is a family physician from Tupelo, MS, and a member of the AMA's Board of Trustees.

Ronald M. Davis, MD
Dr. Davis is director of the Center for Health Promotion and Disease Prevention of the Henry Ford Health System in Detroit, MI. He chairs the AMA's Council on Scientific Affairs and is former director of the U.S. Centers for Disease Control's Office on Smoking and Health. Dr. Davis is also a member of the World Health Organization's Technical Advisory Group on Tobacco or Health and is the editor of the British Medical Association's *Tobacco Control: An International Journal.* He is an alternate delegate to the AMA House of Delegates from the American College of Preventive Medicine.

D. Robert McCaffree, MD
Dr. McCaffree is an internist specializing in pulmonary disease and is chief of staff at the Veterans Affairs Medical Center in Oklahoma City, OK. He is president-elect of the American College of Chest Physicians and is a delegate to the AMA House of Delegates.

John Slade, MD
Dr. Slade is chair of the American Society of Addiction Medicine's Nicotine Dependence Committee and is an internationally renowned expert on nicotine addiction. He has served as a consultant to U.S. and international government agencies on issues of tobacco control.

Ron Levine, MD
Dr. Levine is the State Health Director for the North Carolina Department of Environment, Health and Natural Resources in Raleigh, NC. He represents the Association of State and Territorial Health Officers in the AMA House of Delegates.

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AMA TASK FORCE -- ADD ONE

David R. Holley, MD

Dr. Holley is a radiation oncologist in Monterey, CA, and is a member of the executive committee of the AMA's Council on Legislation.

Michael J. Achinger, MD

Dr. Achinger is a resident in internal medicine at the Wilford Hall Medical Center, Lackland Air Force Base, San Antonio, TX. He is chair of the AMA's Resident Physician Section and an alternate delegate to the AMA's House of Delegates.

Michael W. Bigelow, Ph.D

Dr. Bigelow is completing his medical training at the Medical College of Wisconsin, Milwaukee, WI, and is chair of the AMA Medical Student Section's Governing Council.

Patrick Harr, MD

Dr. Harr is president of the American Academy of Family Physicians, Maryville, MO, and is a delegate from AAFP to the AMA's House of Delegates.

David Callender, MD, MBA

Dr. Callender is deputy chairman of the Department of Head and Neck Surgery at the University of Texas M.D. Anderson Cancer Center, Houston, TX, the world's largest cancer center. He is an adjunct assistant professor of Otolaryngology and Communication Services at Baylor College of Medicine and is a former alternate delegate to the AMA House of Delegates from the AMA Young Physician Section.

PROPOSED TOBACCO SETTLEMENT AGREEMENT

EXECUTIVE SUMMARY AND STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION BOARD OF TRUSTEES

The proposed tobacco litigation settlement represents a landmark effort to overcome the scourge of underage smoking and to achieve substantial and permanent reductions in tobacco use. At the same time, it effectively eliminates the most significant threats of civil liability to the tobacco industry. With these threats eliminated, the tobacco industry will have little incentive to return to the bargaining table. It is essential, therefore, that the settlement produce real, permanent, and major public health benefits. To determine the extent to which it does, the American Medical Association (AMA) commissioned a Task Force, which included members of the AMA Board of Trustees, its House of Delegates, independent physician experts in tobacco control and experienced legal and economic public policy consultants, to undertake a comprehensive analysis of the proposed tobacco litigation settlement from a public health perspective. The Task Force report is attached hereto. The Board of Trustees of the AMA endorses the report and recommendations of the Task Force in their entirety.

The AMA believes that the proposed settlement offers a promising basis for delivering on the required public health benefits. The settlement also has a number of advantages relative to continued litigation and piecemeal legislative reform. For example, the settlement provides funding for public health initiatives and enforcement, and it puts a new regulatory regime in place immediately. On the other hand, critical improvements must be made if the proposed settlement is to produce the desired results.

In particular, two changes are essential. First, the FDA must be given the same authority over tobacco products that it has over other "drugs" and "devices" under the Food, Drug and Cosmetic Act. The only exception should be the 12-year moratorium on any FDA action implementing a prohibition of traditional tobacco products or the elimination of nicotine from tobacco products. The settlement negotiators evidently agreed to this moratorium in order to provide the tobacco industry some predictability about future FDA regulation. But achieving predictability does not require burdening FDA regulation with ill-advised substantive and procedural hurdles that have no public health rationale.

To effectuate this change, the following revisions to the legislation implementing the proposed settlement, or their equivalent, should be adopted:

- There should be a constructional principle indicating that FDA has full authority over all tobacco products and nicotine delivery devices unless a specific exception is expressly set forth in the legislation.

- The settlement should be clarified by eliminating any language that suggests that FDA authority to regulate tobacco products is limited in ways other than the 12-year moratorium.

- FDA should be permitted to use the same procedures, and its decisions should be subject to the same standard of review, that generally apply under the Food, Drug and Cosmetic Act.

- The definition of "tobacco product" should be clarified to include pipe tobacco, cigars, and any other tobacco product.

Second, the Look Back surcharge program designed to create a financial incentive for tobacco companies to reduce underage smoking must be given real teeth. It must provide reasonable assurance that each tobacco company achieves the targets for reduction in underage tobacco use that are set forth in the proposed settlement. If the tobacco industry is to be relieved of any significant civil liability and if FDA jurisdiction is to be subject to a 12-year moratorium for elimination of nicotine, then it is essential that a program of financial incentives be put in place that will guarantee significant reductions in underage smoking.

To effectuate this change, the following revisions to the legislation implementing the proposed settlement, or their equivalent, should be adopted:

- The Look Back surcharge payments should not be subject to the automatic pass through and should not be tax deductible

- The Look Back surcharge payments should be assessed against each individual company based on reductions in underage use achieved by that company. They should not be assessed on the basis of collective industry responsibility.

- The Look Back surcharge payments should be based on the discounted present value of the lifetime social costs of tobacco use, not restitution of profits. We estimate that the penalty should be increased to a level of $400 to $450 million for each percentage of underage use above the target on an industry wide basis (in contrast to $80 million in the proposed settlement).

- The $2 billion cap on annual surcharge payments should be eliminated. Any cap should be based on a multiple of company profits from underage use or on total company profits in the domestic market.

- Tobacco companies that exceed the targets should be given a financial credit. There should be no abatement for compliance with regulations and corporate good faith.

Beyond these essential changes, the AMA strongly recommends the following additional modifications to the proposed settlement.

- The price of cigarettes should be targeted to rise by about $1.00 per pack, as opposed to the $0.62 per pack projected under the proposed settlement. This can be accomplished by an increase in the cigarette excise tax, by upward adjustments in the Annual Payments, or by modifications in the tax treatment of existing Annual Payments.

- The FDA should have authority progressively to tighten the targets of the Look Back program after the ten-year period addressed by the proposed settlement, with a goal of reducing underage tobacco use to incidental levels.

- The preemptive effect of federal youth access restrictions should be narrowed and clarified so that states and local governments may impose civil sanctions on tobacco retailers beyond the federal minimum.

- The preemptive effect of federal advertising restrictions should be narrowed and clarified so that states and local governments may regulate local advertising and marketing and may impose counter-advertising requirements on tobacco companies.

- The restriction on advertising to tombstone-only format should be extended to all publications.

- A federal agency (such as HHS) should be given overall responsibility for disbursement of the Public Health component of the annual Payments, including oversight of grant recipients and authority to make adjustments in allocations in future years.

- The provisions regarding nonsigning companies should be modified so as to avoid erecting unnecessary barriers to new entry.

- The Look Back program should have targets for reduction of underage use of smokeless tobacco identical to the targets for reduction in underage smoking.

Throughout its report, the Task Force recommends a number of additional clarifications or refinements.

If the changes that the Task Force has identified or equivalent changes are adopted by the Administration and Congress, the proposed settlement would be an historic event if the life-or-death struggle to reduce tobacco use to a minimum. Accordingly, the Board of Trustees of the AMA has committed the resources of the AMA to press for the inclusion of these changes in any legislation adopted by Congress.

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News Release

FOR IMMEDIATE RELEASE July 31, 1997

For further information, contact: Brenda L. Craine
202-789-7447

AMA CALLS TOBACCO DEAL "A LANDMARK EFFORT" BUT MODIFICATIONS MUST BE MADE

The American Medical Association today announced support for a "comprehensive legislative solution" to reduce underage tobacco use based on the proposed tobacco settlement agreement -- if Congress adopts critical improvements.

The AMA released a 45-page report, which calls for strengthening the agreement, especially two "essential" provisions that would "achieve real, permanent, major public health benefits." The AMA recommendations would strengthen the FDA's jurisdiction over tobacco products -- so that the FDA is given the same authority over tobacco products that it has over other drugs and devices, and increase the penalty paid by the tobacco industry from $80 million to as much as $423 million for each percentage of underage use above the targets for underage smoking (based on the lifetime social costs of tobacco use).

Richard F. Corlin, MD, speaker of the AMA's House of Delegates, called the agreement a "landmark effort," which contains many otherwise unachievable benefits. The AMA outlined nine advantages to addressing the tobacco problem through an improved version of the proposed settlement, rather than continuing litigation and piece-meal legislation, including the fact that the settlement would generate between $4.5 and $7.5 billion per year in funding for public health programs, would confirm FDA jurisdiction and implement unprecedented youth access and advertising restrictions immediately, and would established an ambitious set of targets for reducing underage smoking.

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202 789-7400

"The danger is that once the tobacco industry gets the relief it seeks, there is no incentive for them to cooperate further," Dr. Corlin said. "In other words, we have to get it right the first time."

The AMA will now turn its attention to gaining public health support and legislative approval for a re-vamped settlement proposal that is modified according to task force recommendations, while offering medicine's input to the Clinton administration as it continues to evaluate the initial settlement proposal.

"We will lobby vigorously for the adoption of these changes as part of any comprehensive legislation passed by Congress and signed by President Clinton," said Randolph Smoak, M.D., AMA Vice Chair. "The AMA's commitment is to help organize a broad-based public health coalition that will engage leaders in Congress and the White House on behalf of America's young people who, for too long, have been seduced by cigarette-makers."

The Task Force report calls for several additional changes in the agreement, including certain " strongly recommended" modifications:

- increasing the price of cigarettes by $1.00 per pack as opposed to the proposed $0.62 per pack;
- allowing the FDA to progressively tighten the Look Back program after ten years with the goal of reducing underage tobacco use to incidental levels;
- clarifying the preemptive effect of federal youth access restrictions so that states and local governments may impose civil sanctions on tobacco retailers beyond the federal minimum;
- expanding the restrictions to tombstone-only advertising for all publications.
- assuring that the Look Back program for reducing underage use of smokeless tobacco is identical to targets for reducing underage smoking.

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ANALYSIS, REPORT, AND RECOMMENDATIONS OF THE AMERICAN MEDICAL ASSOCIATION TASK FORCE ON THE PROPOSED TOBACCO SETTLEMENT AGREEMENT

July 31, 1997

ANALYSIS, REPORT, AND RECOMMENDATIONS OF THE AMERICAN MEDICAL ASSOCIATION TASK FORCE ON THE PROPOSED TOBACCO SETTLEMENT AGREEMENT

George W. Anstadt, M.D., Chair

Michael J. Achinger, M.D.

Michael W. Bigelow, M.D.

David L. Callender, M.D.

Ronald M. Davis, M.D.

Patrick B. Harr, M.D.

J. Edward Hill, M.D.

David R. Holley, M.D.

Ronald H. Levine, M.D.

D. Robert McCaffree, M.D.

John Slade, M.D.

Randolph D. Smoak, M.D.

Staff:

Kirk B. Johnson
Thomas Houston, M.D.
Michael L. Ile
Richard Deem

Consultants:

SIDLEY & AUSTIN
Newton N. Minow
Jack R. Bierig
Michael W. Davis
Thomas W. Merrill
Larry J. Nyhan

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ANALYSIS, REPORT, AND RECOMMENDATIONS OF THE AMERICAN MEDICAL ASSOCIATION TASK FORCE ON THE PROPOSED TOBACCO SETTLEMENT AGREEMENT

Introduction

The proposed tobacco litigation settlement represents an historic opportunity. Structured properly, the settlement could provide a powerful and effective tool for overcoming the scourge of underage smoking and for achieving substantial and permanent reductions in tobacco use. The settlement would also permit these goals to be pursued immediately, without the uncertainty and delay of further litigation.

Yet the proposed settlement is also fraught with peril. It gives the tobacco industry what it most desperately wants: relief from the threat of significant civil liability. It is the threat of such liability, more than anything else, that has brought the industry to the bargaining table. Once that threat is removed, the industry will have little incentive to cooperate further. Thus, it is essential that the settlement produce real, permanent, and major public health benefits.

The Task Force has undertaken a comprehensive analysis of the proposed settlement. We believe the negotiators have produced a framework that provides a promising basis for delivering on the required public health benefits. On the other hand, a number of critical improvements must be made if the settlement is to produce the desired results.

In particular, the Task Force believes that two changes are essential:

- The Food and Drug Administration (FDA) must be given express authority to regulate tobacco products in the same manner, using the same procedures, as would generally apply to drugs and devices, with one exception: FDA would be subject to a 12 year moratorium against implementing action that would ban the sale of traditional tobacco products or require the elimination of nicotine from such products.

- The Look Back surcharge program, designed to provide financial incentives to tobacco companies to achieve stated targets in the reduction of underage smoking, should be given real teeth. As structured in the proposed settlement, this program would be ineffectual. We propose realistic sanctions that assure that the targets for underage smoking reduction set by the negotiators will actually be met.

An ideal legislative package for regulating tobacco products would contain all of the provisions set forth in previous AMA policy statements and many of the elements advocated in

the Koop-Kessler Advisory Committee Report.[1] Such a package might include full, immediate, and complete authority for FDA to regulate all tobacco products and their ingredients; a complete prohibition on tobacco advertising and promotion; a substantial increase in excise taxes on the tobacco products to raise the price of tobacco products; and complete disclosure of all confidential tobacco company documents dealing with the composition of health and safety issues related to tobacco products and marketing efforts.

The proposed settlement falls short of the ideal on these and many other issues. Such, however, is the nature of settlements. The AMA remains committed to achieving all the positions set forth in its existing policy statements. Nevertheless, the fact that the proposed settlement is less than ideal does not necessarily mean that a comprehensive settlement should be rejected from a public health perspective.

There are a number of advantages to addressing the tobacco problem by a comprehensive settlement rather than by continuing litigation and piece-meal legislation. These advantages include the following:

- The settlement would generate between $4.5 billion and $7.5 billion per year in funding for public health programs, including FDA enforcement initiatives. This is far more money than would be appropriated by Congress in conjunction with stand alone legislation or continuation of FDA's current regulatory efforts.

- Because the substantial Annual Payments required by the settlement (rising to $15 billion per year after year four) must be passed through to consumers, the settlement operates like a de facto sales tax increase for cigarettes and smokeless tobacco. It is possible, but highly uncertain, that an explicit sales or excise tax increase of the same magnitude could be enacted in the near future.

- The major tobacco companies would enter consent decrees in which they would promise to abide by restrictions on advertising and other constraints even if the parallel provisions in the legislation were declared unconstitutional. This provides additional assurance that the agreement's advertising controls can be put in place and remain effective.

- The funding generated by the settlement can be disbursed to the states by the federal government, thereby providing a secure constitutional foundation for federal standards for state retail licensing statutes and other desirable measures that might exceed the authority of the federal government to impose on the states directly.

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[1] Final Report of the Advisory Committee on Tobacco Policy and Public Health, Co-Chairs: C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.D. (July 1997).

- A system of financial incentives on tobacco companies is put in place to reduce underage smoking. Imposing a similar system on companies without their consent would be difficult to achieve politically.

- The settlement provides for the establishment of a national tobacco document depository open to the public containing many previously non-public or confidential documents from the files of the tobacco industry. Although tobacco companies can still invoke common law privileges with respect to these documents, stand alone legislation requiring the creation of such a depository would encounter stiff resistance and legal challenges from the companies.

- The settlement provides for the enactment of The Smoke-Free Environment Act of 1993, which adopts tough minimal federal standards for second hand tobacco smoke in all public buildings. It is doubtful that this legislation would otherwise be adopted in this form in the foreseeable future. Although OSHA could promulgate similar rules for worksites under its current authority, to date it has not done so and any such action would be delayed by judicial challenges.

- Resolving tobacco litigation by settlement permits both sides to save litigation costs. These savings can be devoted, in part, to activities with direct public health benefits.

- Perhaps most importantly, settlement allows a new regulatory regime for tobacco products to be put into place immediately. Continuing down the current path of litigation plus efforts to regulate under FDA's and other agencies' existing authority would result in a tobacco control policy that is uncertain, uneven, and burdened by protracted delays.

Taken together, the advantages of settlement suggest that some compromise relative to the ideal package of legislative reforms is justifiable. This does not mean, of course, that the particular compromises contained in the proposed settlement are acceptable.

In this document, the Task Force has endeavored to assess the public health implications of the proposed settlement, suggest clarifications that appear to be within the overall expectations of the negotiators, and recommend certain modifications that we regard as essential if tobacco use -- particularly use by minors -- is to be meaningfully curtailed. We have approached this task as physicians whose primary concern is to promote, preserve, and protect their patients' health. We hope that our analysis will be of assistance to the Administration, the Congress, and members of the public.

The Board of Trustees of the American Medical Association has endorsed the recommendations of the Task Force. It has committed the resources of the AMA to press for their inclusion in any legislation adopted by Congress.

I. FDA Jurisdiction.

The proposed settlement calls for legislation that would expressly confer jurisdiction on FDA to regulate tobacco products. Such legislation would immediately resolve the current legal challenge to FDA's authority, and would place the full weight and authority of Congress and the American people behind FDA regulatory efforts. In these respects, the settlement is clearly desirable.

On the other hand, provisions in the proposed settlement that are likely to limit or frustrate the effectiveness of FDA oversight must be eliminated to the extent possible. The tobacco industry would, of course, like to secure predictability about the future of FDA regulation of tobacco products. Such predictability, however, should not take the form of ill-advised substantive and procedural hurdles that may unduly burden FDA efforts to protect and enhance the public health.

(1) Express Conferral of Jurisdiction on FDA.

Although FDA has asserted jurisdiction over tobacco products under current law, its authority to do so is under challenge.

- Strong arguments have been advanced in support of FDA jurisdiction under current law. Moreover, recent revelations about the intent of tobacco companies to use tobacco products to affect the structure or function of the human body enhance the force of FDA's conclusion that these products meet the legal definitions of "drug" and "device" under the Food, Drug and Cosmetic Act.

- Further, a federal court in North Carolina has sustained FDA's jurisdiction over tobacco products in a thorough opinion.[2]

- Nevertheless, that ruling is now on appeal. Whether the Court of Appeals -- or possibly the Supreme Court -- would ultimately sustain or reject FDA jurisdiction over tobacco products under current law is a difficult question that has divided legal experts.

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[2] Coyne Beahm, Inc. v. Kessler, 958 F.Supp. 1060 (D. N. Car., April 25, 1997).

There thus remains a possibility that the courts will ultimately decide that FDA lacks any authority, or has only limited authority, to regulate tobacco products under current law.

The settlement eliminates this legal uncertainty and expressly confers jurisdiction on the FDA to regulate tobacco products and ingredients, tobacco product manufacturing, marketing, and access to tobacco products.

- Moreover, the adoption of legislation expressly conferring authority on FDA to regulate tobacco would lend legitimacy to the agency's efforts.

- With a new legislative mandate, FDA will be more likely to receive support from the general public for its efforts aggressively to regulate tobacco products.

Of course, Congress has the power to adopt legislation confirming FDA jurisdiction to regulate tobacco products without the settlement. Realistically, however, the chances of such legislation being adopted are greater if presented as part of a settlement that has the support of the tobacco industry.

(2) The Scope of FDA Jurisdiction.

In addition to confirming FDA's jurisdiction to regulate the sale and promotion of tobacco products, the settlement expressly directs FDA to regulate in ways that go significantly beyond that contemplated in the FDA's 1996 regulations, "Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents."[3] For example:

- The FDA would be authorized to promulgate rules governing the testing, reporting, and disclosure of tobacco smoke constituents about which the FDA believes the public should be informed in order to protect public health.

- Manufacturers would be required to provide FDA with a list of all ingredients, substances, and compounds which are added to their tobacco products and, within five years after enactment of the Act, to conduct safety assessments on such additives.

- Manufacturers would be required to notify FDA of any technology that they develop or acquire that reduces the risk from tobacco products and, for a reasonable fee, to license this technology to companies that are subject to the same restrictions. Additionally, FDA would have the authority to mandate the introduction of less hazardous tobacco products that are technologically feasible.

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[3] 61 Federal Register 44396 (August 28, 1996).

- Tobacco product manufacturers would be subjected to good manufacturing practice standards in a manner similar to the oversight exercised by FDA over other drug and device manufacturers.

- FDA would be permitted to adopt "performance standards" that could require the modification of tobacco products to reduce the harm they cause, including (subject to restrictions discussed below) modifications in nicotine content.

These additional forms of regulation could be asserted by FDA on its own authority if its jurisdiction to promulgate the 1996 regulations is upheld by the courts. However, the settlement probably accelerates the timing of these additional forms of regulation.

- If there were no settlement, FDA might wait until all appeals are exhausted before moving to adopt any of the additional regulations contemplated by the settlement. These appeals might not be resolved for several years.

- FDA might also lack funding to take on some of these additional forms of regulation -- something which the settlement provides. Congress has not been eager to increase substantially the funds available to FDA to regulate tobacco products.

(3) **Limitations on FDA's Jurisdiction.**

Ideally, any legislation confirming FDA jurisdiction to regulate tobacco products would permit the agency to adopt any form of regulation consistent with the public interest. This approach may not be possible within the context of a settlement. However, even if it is necessary to recognize some limitations on FDA authority -- at least for a period of time -- those limitations should not include substantive and procedural barriers that have no plausible public health justification and that are likely to frustrate FDA efforts to reduce the adverse public health effects of tobacco use.

Set forth below are several areas in which the proposed settlement imposes unacceptable limitations on FDA authority or where the language is sufficiently ambiguous to require clarification to assure that unacceptable limitations are not created through interpretation.

(a) Except as Expressly Stated, FDA's Authority Over Tobacco Products Should Be No Different From Its General Authority Over Drugs and Devices.

The general approach to FDA authority in the proposed settlement appears to be one of "enumerated powers." The settlement lists and describes a number of categories of FDA authority over tobacco products, including advertising and marketing, youth access, reduced risk products, performance standards, manufacturing oversight, access to company information, and non-tobacco ingredients.

- There is a danger that such an approach will lead to the inference that if a specific power is not granted to FDA, it is by implication denied.

- For example, if FDA is not specifically given authority to regulate flavoring ingredients, can FDA regulate flavorings that have strong appeal to youths (such as cherry flavoring in smokeless tobacco) under its authority to regulate non-tobacco ingredients shown to be "harmful"?

- Similarly, FDA may want to acquire information about, or require companies to perform safety assessments concerning, ingredients contained in substances derived from tobacco, as well as ingredients added to tobacco. It is not clear that the settlement as drafted would permit this (I.F.).

A better approach would be to grant FDA full authority over tobacco products as "drugs" and "devices" under the Food, Drug and Cosmetic Act, subject to express exceptions.

- The burden should be on the tobacco companies to spell out with specificity the ways in which FDA authority to regulate tobacco products as drugs or devices will be limited.

- The burden should not be on government regulators and the public health community to imagine every conceivable issue that might arise in the future, and to devise specific statutory language conferring authority on FDA to tackle the problem.

Any legislation implementing the settlement should therefore include a constructional principle stating that, except as otherwise expressly indicated, FDA has all power and authority to regulate all tobacco products as drugs and devices under the Food, Drug and Cosmetics Act.

(b) Restrictions on the FDA's Promulgation of "Performance Standards."

The most serious and unacceptable limitations on FDA authority are substantive and procedural barriers placed on FDA's authority to issue performance standards requiring the modification of tobacco products to reduce the harm they cause.

The parties to the settlement appear to have reached an understanding to the effect that, for twelve years, FDA may not order a fundamental alteration of traditional tobacco products (for example, by mandating the elimination of nicotine).

- For the first 12 years, FDA "shall be permitted to adopt performance standards that require the modification of existing tobacco products, including the gradual reduction, but not the elimination, of nicotine yields, and the possible elimination of other constituents or other harmful components of the tobacco product" (I.E.5.A.).

- After the first 12 years, FDA may "require the alteration of tobacco products then being marketed, including the elimination of nicotine and the elimination of other constituents or other demonstrated harmful components of the tobacco product" (I.E.5.B.).

Although undesirable, this moratorium is undoubtedly the result of compromise. It may be critical to providing some predictability to the tobacco industry about the future course of FDA regulation.

However, the language that reflects the 12 year moratorium includes a number of troubling ambiguities which should be clarified in a satisfactory fashion.

- The proposed settlement says that FDA may not prohibit "the sale to adults of traditional tobacco products" (I.E.5.). Yet it also says that an FDA order requiring a fundamental alteration (such as the elimination of nicotine) after the 12 year moratorium "shall not be deemed to violate the prohibition on the sale of traditional tobacco products to adults" (I.E.5.B.n.1.). This is confusing and a potential source of mischief. The legislation should clarify that only during the first twelve years after implementation of the settlement is FDA prohibited from banning "the sale to adults of traditional tobacco products."

- In order to require the modification of tobacco products during the first 12 years or direct a fundamental alteration in tobacco products after 12 years, the FDA must find that its regulation "will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard." Such a finding could be virtually impossible to make with

respect to any substance for which there is a strong public demand. The legislation should clarify that demand for contraband is one factor to be considered by FDA as matter of protecting the public health, but is not an absolute precondition to any regulation.

- A footnote in the proposed settlement (I.E.5.B.n.2.) could give rise to a negative inference that FDA's authority to modify tobacco products during the 12-year moratorium does not extend to ordering reductions in nicotine content on the ground that nicotine is addictive (as opposed to finding that it has direct adverse health effects). Any such inference should be disclaimed. Rather, it should be made clear that FDA may order modifications in nicotine content (short of a total elimination) during the moratorium for any reasons that it deems necessary to promote the public health.

Equally troubling are a number of procedural barriers to the regulation of tobacco products that do not generally apply to FDA regulation of drugs and devices.

- FDA rules requiring either the modification or the fundamental alteration of tobacco products are subject to highly cumbersome formal rulemaking proceedings -- as opposed to the informal rulemaking ordinarily used in FDA regulations pursuant to §701(a) of the Act. Informal rulemaking procedures should apply.

- FDA rules requiring either the modification or the fundamental alteration of tobacco products are subject to unusually stringent standards of judicial review. With respect to any action to modify tobacco products, FDA must sustain its findings by "substantial evidence" (as opposed to the usual and somewhat more lenient "arbitrary and capricious" standard). With respect to any action to require fundamental alterations in tobacco products, FDA must sustain its findings by a "preponderance of the evidence" (the standard a plaintiff must satisfy in an ordinary civil trial). The "arbitrary and capricious" standard of review should govern.

- Reviewing courts are instructed to defer to FDA's findings only to the extent that they fall within the agency's "field of expertise." The FDA is not ordinarily required to demonstrate that any particular finding is within its expertise. No demonstration of particular FDA expertise should be required.

- The proposed settlement says that any performance standard requiring a modification of existing tobacco products "shall be subject to the current procedures of the Regulatory Reform Act of 1996 to provide time and a process for Congress to intervene should it so choose" (I.E.5.A.). This appears to be a reference to Section 251 of the Small Business Regulatory Enforcement Fairness

Act of 1996, Pub. L. No. 104-121, which provides that any "major rule" must be submitted to Congress for sixty days to allow Congress to consider enacting a joint resolution of disapproval. Apparently the settlement would mandate that this procedure be followed even if it would not be independently required by the terms of the 1996 Act, or if the 1996 Act were repealed or invalidated. This provision should be deleted.

There is no evident justification for the foregoing procedural limitations other than to erect additional barriers to any FDA regulation of tobacco products -- barriers not generally placed in the way of FDA regulation of drugs and devices. Given the moratorium on any FDA action requiring the fundamental alteration of tobacco products, we see no legitimate justification for these procedural hurdles.

(c) The Definition of "Tobacco Product."

The proposed settlement gives FDA authority over "tobacco products." This term is said to have the same definition as contained in the FDA's 1996 regulations. The settlement also apparently covers "Roll Your Own, Little Cigars, Fine Cut, etc." (I.E.1.).

- Because the FDA in its 1996 regulations elected not to regulate pipe tobacco and cigars, an argument could be made that the regime established by the proposed settlement excludes pipe tobacco and cigars.

- FDA authority to investigate and regulate pipe tobacco, cigars, and all other tobacco products and nicotine delivery devices should be made explicit. Cigar smoking, including such smoking by young persons, is on the rise. This trend may accelerate, especially if the price of cigarettes rises significantly because of the pass through of Annual Payments required by the settlement. Moreover, future forms of tobacco use, e.g., variants on "smokeless cigarettes," cannot be foreseen.

More generally, there is reason to believe that the market for traditional tobacco products containing nicotine and nicotine replacement devices such as inhalers may soon converge. It would be desirable to have all nicotine delivery devices subject to a single integrated regulatory scheme.

- All tobacco products should be subject to a single, comprehensive, regulatory scheme.

- Any legislation enacted as a result of the settlement should be drafted so that eventually all nicotine delivery devices -- whether based on tobacco or not -- are subject to a single, comprehensive, regulatory regime.

II. Advertising and Marketing Restrictions.

The proposed settlement includes restrictions on marketing and advertising that extend beyond the FDA's 1996 regulation.

- FDA's 1996 rules restrict tobacco advertising to FDA approved media; restrict advertising to black text on white background in publications likely to reach minors; ban tobacco billboards within 1000 feet of schools and playgrounds; require tobacco products and advertisements to include the label "nicotine delivery device;" ban the use of promotional merchandise; ban offers of gifts; and ban sponsorship of concerts and sporting events.

- The proposed settlement would incorporate requirements at least this restrictive in the legislation.

- In addition, the settlement would ban all use of human images and cartoon characters in any advertising; ban all billboard advertising; prohibit tobacco advertising on the Internet; ban indirect payments to movies and music videos to glamorize smoking; require new and more emphatic warning labels ("WARNING: Smoking can kill you", etc.); and require that warning labels comprise 25% of front panels of packages.

(1) First Amendment Issues.

One issue raised by these advertising restrictions is whether they will survive judicial challenge based on the First Amendment.

- We believe that the courts would ultimately uphold the FDA's 1996 advertising regulations, given the record compiled by FDA showing a compelling public health rationale for reducing underage smoking, and the fact that FDA's regulations are limited to media likely to be seen by minors.

- Because the provisions of the proposed settlement go beyond the FDA regulations, they would likely encounter a more vigorous First Amendment challenge.

- We do not suggest that these provisions cannot be defended with equal vigor, nor do we believe that they would be struck down. But the probability of sustaining them would be somewhat lower than is the case with respect to the FDA regulations.

- In order to maximize the chances that all advertising restrictions will be upheld, any legislation resulting from the proposed settlement should include express

findings and statements of purpose that emphasize the importance of reducing smoking among adults as well as minors. Such findings and statements of purpose would make it easier to justify the extension of advertising regulation to adult media.

One advantage of the proposed settlement is that it creates a mechanism for increasing the chances that the agreement's advertising regulations will endure regardless of the outcome of First Amendment challenges. The settlement provides that the parties will enter into consent decrees, in which they will "expressly waive any claim that the provisions of the consent decrees or the agreement violate the federal or state constitutions" (III.B.bullet 5.). In addition, "[t]he consent decrees will also state that if a provision of the Act covered by the decrees is subsequently declared unconstitutional, the provision remains an enforceable term of the consent decrees" (id.).

- In other words, the signatories to the proposed settlement -- including, of course, the major tobacco manufacturers -- will be bound to observe the advertising restrictions by judicial decrees as well as by statutory regulation.

- If the statutory law is invalidated on constitutional grounds, the signatories would continue to be required to abide by those restrictions.

There is some danger that this "waiver of rights" provision might be struck down under what is called the "unconstitutional conditions" doctrine.

- But the parties to the consent decrees are sophisticated and clearly understand their rights; the government has an important interest in obtaining a waiver; and the speech involved is commercial speech that can be subjected to a greater degree of government regulation. The unconstitutional conditions doctrine should therefore not cause the waiver of rights provision to be invalidated.

- The waiver of rights feature of the settlement substantially increases the probability that important advertising restrictions can be put into place in the near future.

(2) Tombstone-Only Advertising in All Publications.

Although the proposed settlement would ban image advertising in publications that reach a substantial portion of juvenile readers (15% or more), it would continue to permit color graphics, landscapes, and other evocative images in publications that serve a predominantly adult audience.

- Such image advertising serves no purpose other than to make tobacco products more attractive and hence to stimulate demand for their use.

- To the extent that image advertising affects overall levels of smoking, it represents a serious public health concern, whether the target of the advertising is adults or adolescents.

- Also, of course, some image advertising in publications primarily read by adults will also reach adolescents and children.

- Perhaps most importantly, the presence of image advertising in publications helps to reinforce a social attitude that smoking is acceptable. This attitude helps to perpetuate smoking by adults and increases its allure for teens.

Therefore, the Task Force recommends that the tombstone-only restriction on tobacco product advertising be extended to all publications, including those that have a predominantly adult audience.

(3) Advertising Restrictions As A Five Year Trial Period.

The AMA House of Delegates has previously adopted a resolution advocating the complete prohibition of tobacco product advertising.[4] We do not regard the proposed settlement as inconsistent with this resolution, or as precluding its eventual realization.

- The proposed settlement provides that the advertising restrictions it imposes "shall be allowed to operate" for five years. Thereafter, "the FDA would be authorized to review and revise the rules under applicable Agency procedures" (I.introduction.).

- It appears, therefore, that FDA is free to revisit the advertising restrictions after 5 years and, if it deems it appropriate, to adopt tougher restrictions, such as a complete ban on tobacco advertising.

On this understanding, we believe that allowing the restrictions of the proposed settlement to take effect for a five year trial period -- especially if supplemented by requiring tombstone advertising in all print media -- is an acceptable first step in dealing with tobacco advertising.

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[4] AMA Policy No. 500.980, AMA Policy Compendium (1997 ed.).

- Other nations are moving rapidly to adopt limits on tobacco advertising more restrictive than those contained in either FDA's regulations or the proposed settlement. During the five year period in which the settlement provisions are in effect, additional information can be gathered about the effectiveness of these regulations. These studies will provide additional experience and knowledge on which to base further FDA action.

- It is also important to note that the proposed settlement calls for the expenditure of $500 million per year on counter-advertising. Again, it will be useful to study the effect of this major commitment of resources to counter-advertising, in order to determine whether additional counter-advertising might prove to be a promising strategy for FDA to pursue in the future.

(4) Miscellaneous Clarifications.

There are a few other areas in which clarification or elaboration of the advertising regime that will be in place for the next five years is warranted.

- The proposed settlement provides that "[c]urrent federal law providing for national conformity of warning labels, packaging and labeling requirements, and advertising and promotion requirements related to tobacco and health is preserved" (V.B.2.). This should be clarified by the adoption of an explicit preemption and savings clause that supersedes existing preemption provisions of the Federal Cigarette Labeling and Advertising Act. Federal regulations should preempt state advertising regulation only in media that are distributed in interstate commerce. States should remain free to adopt more stringent regulations of local print advertising, point of sales advertising, promotional allowances, sampling distribution, and coupons.

- States should also be free to tax tobacco companies to fund counter-advertising beyond the levels provided for in the proposed settlement (as under the current California program).

- The prohibition on sponsorship should also be clarified to preclude tobacco company sponsorship of any computer software, Internet, or video products that utilize human or animal images or cartoon characters associated with smoking or that glamorize use of tobacco.

III. Restrictions on Youth Access.

The proposed settlement includes restrictions on access to tobacco products by minors that go considerably beyond the FDA's 1996 regulation.

- FDA's 1996 rules adopt a national minimum age for purchase of 18; require retailers to verify age by photographic ID; prohibit vending machines in places frequented by persons under 18; and ban sampling of tobacco products.

- The proposed settlement would incorporate requirements at least this restrictive in legislation.

- In addition, the settlement would require that all sales of tobacco take place through face-to-face transactions (no vending machines).

- Another important new provision regarding access is a national licensing scheme for retail tobacco product sellers.

- Finally, the proposed settlement includes a number of provisions designed to encourage greater state efforts to enforce laws regarding sales of tobacco products to minors.

In general the licensing and state enforcement provisions appear to represent a substantial advance beyond the program adopted by FDA in August 1996.

The access provisions should be drafted to avoid the constitutional problems that led the Supreme Court recently to invalidate portions of the Brady Bill.[5]

- With proper drafting, it would appear that virtually all of the access regulations can be implemented as conditions attached to federal grants given to states.

- Further consideration should therefore be given to the mechanics of the flow of funds from the tobacco companies to the states, in order to assure that the grants to the states properly qualify as "federal funds" and thus that the conditions imposed on receipt of those funds satisfy constitutional requirements.

In addition, the enforcement provisions of the access regulations should be strengthened. The civil sanctions set forth in Appendix II, in particular, provide for very modest civil fines and suspension periods for selling tobacco products to minors. A retailer's license is to be permanently revoked only "for the tenth offense within any two year period."

- These wholly inadequate civil sanctions can aptly be described as "ten strikes and you're out."

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[5] Printz v. United States, 65 U.S.L.W. 4731 (June 27,1997).

- Moreover, the civil sanctions are set forth as a federal maximum which the states "shall not exceed."

- Given that the proposed settlement expressly retains authority in the states to impose state criminal sanctions on retailers who sell to minors, there is no sound rationale for preemptive federal standards limiting states to nothing but the most modest civil sanctions.

- In formulating any legislation to implement the settlement, Congress should change this federally-imposed schedule of civil sanctions from a maximum to a minimum.

More generally, it is important to preserve the role of state and local governments in developing and enforcing access restrictions.

- In addition to being allowed to adopt civil penalties for violation of licensing requirements that go beyond the federal minimum, states should be allowed to experiment with additional enforcement tools, such as citizen suits and the use of consumer protection statutes.

- States should also be allowed to make it a criminal or civil offense for any person, not just a retailer, to sell cigarettes to a minor.

In addition, all too often federal PXs and commissaries serve as major sources of supply of cheap and readily accessible cigarettes to local communities.

- State and local access restrictions should be extended by statute to federal enclaves and federal facilities, including military bases and hospitals. The manner in which these state and local rules would be enforced at federal facilities should be determined by Executive Order.

- In addition, we recommend that a federal use tax -- equal to federal, state and local excise and sales taxes otherwise applicable in the area -- be imposed on tobacco products sold at federal enclaves and facilities. Consideration could be given to dedicating the proceeds of this tax for the benefit of federal service personnel and employees at these federal facilities.

IV. Economic Incentives -- Smokers.

Economists and other public health policy analysts believe that one of the most effective measures for discouraging the initiation of youth smoking and reducing the prevalence of smoking by adults is to increase tobacco product prices. Higher prices

Payments through to customers in the form of higher retail prices. The net result can be described as a de facto sales tax increase.

- Like a sales tax, the price increases resulting from the automatic pass through will presumably be uniform throughout the industry and uniform with respect to each unit of product.

- Like a sales tax, the price increases will provide funding for worthy public projects, except now the allocation of the funds would be determined by settlement agreement rather than by Congress.

(1) Interpreting the Pass Through.

The magnitude of the price increases generated by the automatic pass through depends critically on how the imprecise language of the automatic pass through provision is interpreted.

- Most readers of this language assume that the way the tobacco companies would "reflect" Annual Payments in prices would be simply to add the additional cost associated with the Annual Payments to the unit retail price of tobacco products. We refer to this assumption as the "constant cost" interpretation. Under this reading, overall prices would rise by an amount equal to the Annual Payments, and, since consumption probably would decline as a result of the higher prices, net income realized by the tobacco companies from domestic sales would likely decline.

- Conceivably, however, the language could be read to permit the tobacco companies to "reflect" Annual Payments in prices in a manner that would prevent the loss of net income as a result of declines in volume of sales caused by price increases. We refer to this reading as the "constant income" interpretation. Under this interpretation, prices would have to be raised by an amount even higher than the Annual Payments, in order to offset the lower volume of sales. Because the tobacco companies would enjoy higher profits per unit sold, their net income would remain constant notwithstanding lower sales volumes.

- A variation of the constant income interpretation is introduced by virtue of the exemption from the antitrust laws afforded the tobacco companies in order to take action in furtherance of the settlement's goals.[6] We refer to this variation as the "profit maximization" construction. Under this approach, the tobacco

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[6] As noted above, the manufacturers will be required to obtain Justice Department approval of any plan for concerted action pursuant to the exemption.

discourage initial use, reduce smoking by current smokers, and increase the rate at which such smokers quit.

- The effect of price on consumption is especially pronounced for underage smokers, who have less disposable income and are less likely to be already addicted.

- Each price increase of 10% is expected to lead to a decline of 4% in the number of cigarettes sold in the short run, and a 10% decline in the number of new smokers.

The proposed settlement contains a program for increasing the price of tobacco products, although it is not separately described as such. Three provisions in the proposed settlement work together to create this program.

- The proposed settlement states: "In order to promote maximum reduction in youth smoking, the statute would provide for the Annual Payments to be reflected in the prices manufacturers charge for tobacco products" (VI.B.7.). We refer to this provision as the "automatic pass through."

- Appendix IV states: "In order to achieve the goals of this Agreement and the Act relating to tobacco use by children and adolescents, the tobacco product manufacturers may, notwithstanding the provisions of the Sherman Act, the Clayton Act, or any other federal or state antitrust law, act unilaterally, or may jointly confer, coordinate or act in concert, for this limited purpose. Manufacturers must obtain prior approval from the Department of Justice of any plan or process for taking action pursuant to this section; however, no approval shall be required of specific actions taken in accordance with an approved plan" (App. IV.C.2.).

- The final piece of the picture is provided by the annual Volume Adjustment provision. If in any given year the volume of domestic sales exceeds the level of 1996 domestic sales, the annual payment for that year is increased in proportion to the increase over 1996 sales. On the other hand, if there is a decrease in volume sales over the 1996 base year, manufacturers are entitled to a proportionate reduction of the annual payment obligation (provided, however, that sales to non-adults are excluded for purposes of calculating a decrease in volumes).

Taken together, these three provisions indicate that the Annual Payments obligation will move up and down in relation to sales volume, and that the tobacco companies will meet together periodically to develop a common plan for passing these volume-adjusted Annual

companies, relying upon the exemption from the antitrust laws, would collectively set prices in excess of that which is necessary to pass through Annual Payments or preserve net income, ostensibly for the purpose of further discouraging consumption. Given the oligopolistic structure of the industry and the relative inelasticity of demand for cigarettes, this approach could significantly enhance the profitability associated with domestic sales, although it probably would also pose the most significant deterrent to consumption.

It is unclear whether the profit maximization approach is within the contemplation of the parties to the proposed settlement.

- To avoid the serious inequities that the profit maximization approach would create, the statutory language should be drafted to make clear that the antitrust exemption will not permit the tobacco companies to act in concert in order to achieve profit maximization.

- Whether legislatively to impose the constant cost or the constant income interpretation is a more difficult issue.

- From a public health perspective, the constant income interpretation would have one desirable consequence: It would raise tobacco prices even higher than they would rise under the constant cost interpretation, resulting in further reduction in consumption and lower rates of initiation.

- However, these benefits would come at the expense of completely insulating tobacco company shareholder value from the direct and indirect costs associated with the settlement.

- We take no position on this issue, other than to note that adoption of the constant income interpretation would provide an additional justification for modifying the Look Back surcharge (discussed below) in ways that would impose powerful economic incentives on tobacco companies.

(2) Tax Deductibility.

Another important variable is tax treatment. The proposed settlement provides that Annual Payments and Look Back surcharges are to be deemed ordinary and necessary business expenses in the year incurred and hence will be fully tax deductible (VI.D.).

As a general matter, we believe that the payment obligations imposed by the proposed settlement should treated for tax purposes the way analogous obligations are treated under the law. Under this standard, the proper tax treatment of the Annual Payments is debatable.

- On the one hand, the Annual Payments could be regarded as payments made in the settlement of litigation, which are usually regarded as tax deductible. Or they could be regarded as a kind of excise tax, which also may be deducted as an ordinary and necessary business expense.[7]

- On the other hand, the Annual Payments could be regarded as akin to a civil fine or penalty imposed by law in order to deter tobacco companies from engaging in conduct that violates public policy.[8]

- We take no position on how Congress should resolve the tax treatment of the Annual Payments, except to note that the resolution of this issue will have an impact on the magnitude of the price increases that flow from the settlement.

(3) Public Health Benefits of Price Increases.

Unlike many of the other benefits of the proposed settlement, the public health benefits of a price increase are susceptible to quantitative estimation.

- The proposed settlement, with its existing schedule of Annual Payments and automatic pass through, should result in an increase in the price of cigarettes of $0.62 per pack to an estimated average of $2.67.[9]

- Given consensus estimates about the price elasticity of demand, this translates into an estimated 10% decline in tobacco consumption and an estimated 23% decline in youth consumption.[10]

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[7] See 26 CFR 1.164-2(f).

[8] See 26 U.S.C. §162(f).

[9] This is the increase in year five under the settlement when the Annual Payments equal $15 billion. See Exhibit A attached to this Report. Increases in price in years one to four would be lower. The current average price of cigarettes is $2.05 per pack. See Economic Research Service, U.S. Dept. of Agriculture, Tobacco, TBS-278, Tables 1,33 (Washington D.C., May 5, 1997).

[10] We have assumed an overall price-elasticity of demand of -.4 and a price elasticity of adolescent demand of -1.0, in line with most economists' estimates. See, e.g., J. Harris, A Working Model for Predicting the Consumption and Revenue Impacts of Large Increases in the US. Federal Cigarette Excise Tax, National Bureau of Economic Research Working Paper No. 4803 (Cambridge, MA: National Bureau of Economic Research, July 1994); G.S. Becker, M. Grossman, and K. Murphy, An Empirical Analysis of Cigarette Addiction,

(continued...)

Significant additional benefits would be realized by even higher price increases. Congress should therefore take additional steps, either as part of legislation implementing the settlement or in independent legislation, to push retail tobacco prices to even higher levels.

- Exactly how high prices should be set in the short run entails a weighing of competing factors.

- Economists have estimated that price would have to rise to slightly more than $4.00 per pack before the revenue losses associated with declining sales would overtake the increase in profits due to higher prices.[11]

At a minimum, an immediate price increase in the magnitude of $1.00 per pack should be considered.

- Such an increase would generate measurable additional benefits beyond the $0.62 per pack increase that would result from the proposed settlement.

- We estimate that a $1.00 per pack increase would translate into a 15% reduction in overall consumption, and a 33% reduction in adolescent consumption.

There are at least three ways to achieve an additional price increase to the level of approximately $1.00 per pack.

- One would be to increase the federal excise tax on cigarettes. The Kennedy-Hatch Child Health Insurance and Lower Deficit Act that nearly passed the Senate earlier this year called for a $0.43 increase in the cigarette excise tax. Adopting such a provision in conjunction with legislation implementing the proposed settlement would generate a price increase approximately in the $1.00 per pack range.

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[10] (...continued)
National Bureau of Economic Research Working Paper No. 3222 (Cambridge, MA: National Bureau of Economic Research, March 1993); T.E. Keeler, T. Hu, P.G. Barnett, and W.G. Manning, "Taxation, Regulation, and Addiction: A Demand Function for Cigarettes Based on Timeseries Evidence," 118 Journal of Health Economics 12 (1993).

[11] Jeffrey E. Harris, "American Cigarette Manufacturers' Ability to Pay Damages: Overview and Rough Calculation," 5 Tobacco Control 292-294 (1997).

- Alternatively, the Annual Payment obligations under the proposed settlement, which are subject to the automatic pass through, could be increased by $9 billion per year above the proposed level of $15 billion per year to $24 billion per year.

- A third option would be to make the Annual Payments nondeductible for income tax purposes but then permit tobacco companies to engage in collective price setting to offset the impact of nondeductibility.[12]

V. Economic Incentives -- Tobacco Companies.

The proposed settlement includes an important provision designed to provide financial incentives to tobacco manufacturers to achieve the overriding goal of reducing underage smoking. This provision is the so-called "Look Back" surcharge. The proposed settlement's attention to the issue of financial incentives for tobacco companies represents an important breakthrough. However, the structure of incentives adopted for manufacturers is fundamentally flawed. Indeed, the public health benefits of the Look Back surcharge program, as currently formulated, would be negligible or negative.

It is absolutely essential that the Look Back program achieve its stated goals if the proposed settlement is to serve the public interest. Given that the settlement eliminates the risk of significant civil liability to tobacco companies, and given that FDA's jurisdiction over tobacco products is curtailed for the period of the 12-year moratorium, the only guarantee that the settlement will produce real, permanent, and major reductions in consumption and youth initiation has to come from the Look Back program.

In brief summary, the proposed Look Back surcharge program contains the following elements (II.; App.V.).

- Targets are set for reductions in underage smoking: 30% of current underage smokers by years 5-6, 50% by years 7-9, and 60% by year 10 and thereafter. More modest targets are set for smokeless tobacco: 25%, 35% and 45%.

- Tobacco manufacturers will be assessed a surcharge for each percentage point by which the industry as a whole fails to meet these targets. The surcharge is set at $80 million per percentage point for the whole industry, to be prorated

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[12] If payments are nondeductible, but tobacco companies could engage in collective action to negate this effect, then presumably they would be permitted to raise prices so that the after tax increase in their margin equals 62 cents. Assuming a marginal corporate income tax rate of 35%, the price increase would be 62/(1-.35) = 95 cents. This would result in an increase to $3.00 per pack.

among manufacturers in accordance with their overall market share. The $80 million figure is said to represent the present value of the profit the industry would earn over the life of 1% of underage smokers.

- Total annual surcharge liability is, however, capped at $2 billion.

- In addition, individual tobacco companies may apply to FDA for an "abatement" of up to 75% of their share of the surcharge, upon a showing that they have acted in good faith and in full compliance with all requirements of the act.

- The surcharge "will be reduced to prevent double counting of persons whose smoking had already resulted in the imposition of a surcharge in previous years."

- Although the proposed settlement is not explicit about this, it appears to be contemplated that surcharge payments, like other Annual Payments, would be subject to the automatic pass through.

- The surcharge, like the Annual Payments, is fully tax deductible (VI.D.).

The proposed Look Back surcharge contains a number of unacceptable features. Cumulatively, these defects mean that tobacco manufacturers will have very little incentive under the program to reduce underage smoking. Indeed, it is conceivable that the program in its proposed form could create an incentive for tobacco companies to increase their share of the underage market. Six different features of the Look Back surcharge must be changed if this program is to perform an effective role in the overall settlement. Moreover, FDA must play a role in establishing and implementing a Look Back surcharge program.

(1) Automatic Pass Through and Tax Deductibility of the Surcharge.

If the Look Back surcharge is to function as an incentive for manufacturers (as opposed to smokers), it must not be subject to the automatic pass through. If surcharge payments are simply passed through to consumers, then the surcharge will constitute nothing more than an additional increment in Annual Payments liability that shows up as a small increase in consumer prices (estimated to be approximately $0.08 per pack of cigarettes if manufacturers are subject to the full $2 billion annual surcharge). This would have some (very modest) additional effect in depressing consumption of tobacco products. But the dollar-for-dollar shift in liability from manufacturers to consumers would eliminate any incentive for manufacturers to change their behavior.

The Look Back surcharge therefore should not be subject to the automatic pass through rule.

- The legislation implementing the settlement should also make clear that tobacco companies will not be allowed to act in concert to agree upon a pass through of the surcharge to consumers.

- Tobacco companies may still be able to recover some of the costs associated with Look Back surcharge payments. But they will be able to do so only insofar as competitive conditions in the market would permit them to raise prices independently of whatever actions are taken by their competitors.[13]

Further, the Look Back surcharges should not be tax deductible. Rather, the tax treatment of the payment obligations under the proposed settlement should be based on the way in which closely analogous obligations are treated under current tax law.

- The Look Back surcharge is most closely analogous to a civil fine or penalty imposed under federal law in order to deter companies from engaging in conduct that violates public policy.

- Under the Internal Revenue Code, no tax deduction is allowed for civil fines or similar penalties, such as treble damages for antitrust violations.[14]

- Moreover, manufacturers should not be permitted to act in concert to raise prices to offset the effect of the denial of tax deductibility.

- The denial of tax deductibility, like the elimination of the automatic pass through, is necessary in order to bring the full deterrent impact of these payments home to the companies.

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[13] Legislation that would go further and prohibit any attempt on the part of tobacco companies to pass through Look Back surcharges would probably be futile unless the FDA is prepared to engage in comprehensive oversight of all tobacco company pricing decisions in order to determine that they are justified by costs other than surcharge payments.

[14] See 26 U.S.C. §§ 162(f), 162(g). These Code provisions are a codification of Tank Truck Rentals, Inc. v. Commissioner, 356 U.S. 30, 36 (1958), which reasoned that a trucking company should not be allowed to deduct fines incurred for operating trucks in excess of state weight limits because this would "frustrate state policy in severe and direct fashion by reducing the 'sting' of the penalty."

(2) Collective Responsibility for the Surcharge.

The Look Back surcharge in the proposed settlement is based on a principle of collective responsibility. The annual penalty is calculated on the basis of the collective performance of the industry each year in reducing underage smoking, with the penalty then apportioned among companies according to their share of the total market (adult as well as minors).

This collective responsibility feature establishes a "tragedy of the commons" in which each company, perversely, would have an incentive to increase rather than decrease its share of the underage market. The problem, in a nutshell, is that each company would capture the added profits from increasing its share of the underage market, but the penalties for this behavior would be spread among all companies in the industry.

A simple numerical example illustrates the problem.

- Assume that the tobacco market is served by two companies, Company A and Company B, and that each initially has 50% of both the total and the underage market.

- Assume further that in a certain year Company A adopts a marketing campaign to increase its share of the underage market. It succeeds in capturing an additional 2% of that market, which under the assumptions of the proposed settlement means an additional profit having a discounted present value of $160 million.

- Meanwhile, Company B adjusts its marketing strategy so as to reduce underage consumption of its products. It succeeds in achieving a reduction equal to 2% of the underage market. This translates into a loss having a discounted present value of $160 million.

- Assume further that the industry misses its target for reducing underage smoking in this year by 1%. This translates into a collective Look Back surcharge of $80 million.

- The financial consequences to the two companies are set forth in Table 2. Company A, the bad corporate citizen, gets an additional profit of $160 million offset by a penalty of $41.6 million, for a net gain of $118.4 million. Company B, the good corporate citizen, experiences a loss in profit of $160 million augmented by a penalty of $38.4 million for a total loss of the $198.4 million.

Table 1

	"Bad" Company A	"Good" Company B
Starting Market Share[15]	50%	50%
Market Share Gain/(Loss) during Year 1	2%	(2%)
Market Share at Year 1 End	52%	48%
Surcharge ($80 million) Allocation	(41.6) million	(38.4) million
Gained/(Lost) Profits	160 million	(160) million
Net Change in Position in Consequence of Changed/Market Share and Surcharge Imposition	118.4 million	(198.4) million

The lesson of the existing Look Back surcharge program for tobacco companies could not be more inappropriate: It pays an individual company to be a bad corporate citizen and to try to increase its share of the underage market. A good corporate citizen which succeeds in reducing its share of that market is penalized. Any legislation that incorporates the collective responsibility feature of the proposed Look Back surcharge is therefore unacceptable.

The University of Michigan's National High School Drug Use Survey, whose methodology the proposed settlement adopts for calculating both the base percentage and the annual percentage of underage use, is not designed to measure underage smoking by manufacturing company. Nevertheless, we see no insuperable barrier to developing an accurate national survey of underage use by company.

- For example, the CDC's Teenage Attitudes and Practices Survey (TAPS) has undertaken surveys of youth smoking by brand name.[16]

- Thus, either the University of Michigan survey method could be modified to measure underage use by brand, or a different sampling method could be developed that would survey for underage use by brand.

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[15] The hypothetical assumes that initially overall market share is equal to underage market share.

[16] Center for Disease Control, "Changes in the Cigarette Brand Performances of Adolescent Smokers - United States, 1988-1993," 93 Morbidity and Mortality Weekly Report 577-581 (August 19, 1994).

- Once underage use by brand is determined, it should be easy to calculate underage use by manufacturing company.

(3) Use of Profits Rather Than Social Costs.

The proposed Look Back surcharge is based on a principle of restitution of profits earned by tobacco companies in selling to the underage market. A more appropriate measure would be based on a principle of internalization of the social costs associated with use of tobacco products.

Requiring tobacco companies to disgorge the profits they earn in introducing minors to tobacco products leaves them at best indifferent to whether or not youth smoking occurs. If the incentives are to work, tobacco companies should be forced to internalize the social costs associated with underage smoking. Only by forcing the tobacco companies to bear the social costs of underage smoking will they have the proper incentive to take all measures which would be socially justified to reduce these costs -- including redesigning their products to increase quit rates or to lower the lifetime health risks associated with using their products.

Social costs also provide a better measure than purely external costs.

- If this were an incentive program to reduce adult smoking, then perhaps an argument could be made that adult smokers are responsible for the costs that they and their families bear. The fact that tobacco products are highly addictive, however, makes it difficult to assume that even adults who start smoking have accurately calculated either the lifetime costs that they and their families will bear, or the "benefits" they derive from smoking.

- The Look Back program is not addressed to adult smoking, however. Rather, it is designed to create an incentive for companies to prevent smoking by adolescents, some of whom are 10 years old or younger.

- Given the immaturity and the limited experience of this cohort, it makes little sense to assume that adolescents have accurately accounted for the long-term consequences of this highly addictive product.

We recommend that the social costs of underage smoking be determined by FDA using the "cost of illness" methodology developed by Dr. Dorothy Rice and utilized by the CDC.[17]

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[17] D.P. Rice, Estimating the Cost of Illness, Health Economic Series, no. 6, DHEW Publication No. (PHS) 947-6 (Rockville, MD: Department of Health, Education, and Welfare, (continued...)

- This method relies on two factors: the lifetime medical costs attributable to smoking and lost wages due to premature morbidity and mortality.

- This measure of social costs is thus conservative, since it does not attempt to measure the value of lost years of life when wages are no longer being earned, loss of consortium to family members caused by premature deaths, the costs associated with second hand smoke, etc.

FDA should develop the costs of illness measure through rulemaking, and should revise the number periodically in order to reflect new data about medical costs, quit rates, and so forth.

- This process of periodic revision would provide a powerful incentive to companies not only to come up with new ways to prevent youth smoking, but also ways to reduce the lifetime costs of using their products.

- For this reason, the social cost measure will provide indirect benefits to adult smokers as well as to adolescents who never start smoking.

We have attempted to develop a preliminary estimate of the social cost measure under the costs of illness methodology using conservative assumptions.

- To do so, we adjusted the most recent cost of illness estimate published by the CDC[18] for wage and medical inflation.

- We also adopted, to the extent possible, the same assumptions as to discount rate, inflation, etc. as were employed in developing the $80 million life profit figure under the proposed settlement.

- We assumed a period of 50 years between the time a smoker begins smoking and the onset of smoking-related disease. Some might argue that the period is significantly shorter. To the extent that it is, we have chosen to err on the conservative side.

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[17] (...continued)
1966): D. P. Rice, T.A. Hodson, and A. N. Kopstein, "The Economic Cost of Illness: A Replication and Update," 7 Health Care Financing Review, 61-80 (1985).

[18] Center for Disease Control, "Medical-Care Expenses Attributable to Cigarette Smoking -- United States, 1993," 42 Morbidity and Mortality Weekly Report 469-472 (July 8, 1994).

Following this approach, we estimate that the present value of the lifetime social cost of underage smoking would be within a range from $400 to $450 million for each percentage point by which the industry misses its target.[19]

- This figure is much larger than the expected profits figure, for the simple reason that the social costs of smoking are so staggering in their magnitude.

- This figure thus underscores the great urgency, from a public health perspective, in achieving rapid and permanent reductions in the incidence of underage smoking. Adoption of social costs as the measure of the Look Back surcharge would harness the energy of the industry to achieve those reductions.

As an alternative to the social cost measure, Congress could also consider adopting a measure of the Look Back surcharge based on the lesser of social costs or a multiple of profits.

- For example, the surcharge could be based on the lesser of (i) the lifetime social cost per percentage point above the target, (ii) three times the lifetime profit per percentage point above the target, or (iii) the company's net profit from domestic tobacco sales for the year.

- Although a mixed rule lacks the conceptual clarity of the pure social cost measure, it nevertheless would also provide a strong incentive for tobacco companies to achieve the targets for underage smoking reduction.

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[19] Following the cost of illness methodology, the CDC has estimated that the medical costs attributable to smoking in 1993 were $50 billion and that the lost wages associated with premature morbidity and mortality totaled $47.2 billion in 1990. Adjusting these figures for wage and medical inflation, the total cost of smoking in 1996 would equal about $115 billion or $4.72 per pack of cigarettes. According to the data used in the settlement to calculate the average profit per underage smoker, an adolescent smoker can be expected to consume 23,129 packs over the course of his or her lifetime. This translates into a lifetime social cost of $109,169 per adolescent smoker. However, this figure must be discounted, since the medical and productivity costs associated with smoking illness tend to occur later in life. If we assume that, on average, these costs are incurred 50 years after initiation, and discount at 4 percent after inflation, then the present value of the social costs of smoking are $15,361 per adolescent smoker. Applying this to the penalty mechanism in the Look Back provisions would increase the penalty per percentage point of underage smoking above target from $80 million to $423 million.

(4) The $2 Billion Annual Cap.

The $2 billion cap on annual industry Look Back penalties is unacceptable, especially if the program is reoriented along the lines of a social cost internalization program, as described above.

- Even if the Look Back surcharge payments could not be automatically passed through and were not tax deductible, the $2 billion cap would still represent an arbitrary limit on the capacity of the surcharge program to impose on the companies the full costs of their actions. It would thus undercut their incentives to devise ways of inhibiting underage tobacco use.

- At an estimated social cost rate of between $400 and $450 million per percentage point, the $2 billion cap would impose no additional penalty once the target was missed by 4.0 to 5.0%.

We are not, however, inalterably opposed to a cap under any circumstances. Whether a cap is appropriate, and, if so, in what amount, depends on how other elements in economic picture are resolved.

- However, any cap should take the form of the "lesser of" alternative to the pure social cost measure of the surcharge.

- Such a cap would provide assurance that no company would face insolvency because of its failure to meet the underage smoking targets, but would also preserve a very powerful deterrent.

(5) Rewards for Companies that Exceed the Targets.

The Look Back program should contain a system of rewards for companies that exceed the stated targets. Those rewards, however, should be based on achieving actual results, not persuading regulators that the company has acted in good faith and full compliance with the law.

- The incentive system should be directed at stimulating companies to do whatever it takes to lower underage smoking, whether those steps are required by existing regulations or not.

- For example, it may be that in order to discourage youth smoking, companies should stop producing certain brands, or should modify flavoring ingredients, or should stop selling in certain types of retail outlets, or should launch their own counter-advertising campaign. None of these steps is mandated by the proposed

settlement. However, each is something each tobacco company can do on its own initiative in order to reduce teen tobacco use of its products.

- The abatement provision in the proposed settlement, in contrast, creates an incentive for companies to foster the appearance of "corporate compliance" and to make elaborate presentations to regulators about corporate good faith. We believe that corporate compliance programs can be valuable, but would urge that any incentive system be based on real results, not rhetoric.

In lieu of an abatement based on compliance with regulations and good faith, we recommend that provision be made for a system of monetary credits for companies that exceed the stated targets for reductions in underage smoking.

Such a system of monetary credits, like the surcharge, should be based on costs -- in this case the costs to the tobacco manufacturing company of exceeding the legislated targets.

- That cost is the foregone profit that the tobacco company would earn by attracting additional underage smokers to its products. This figure is stated to have a present value of $80 million for the industry per percentage point of the underaged market served. (The actual number for each company should be determined by FDA through rulemaking.)

- Thus, while the penalty for failing to reach the target should be based on the costs to society (estimated to the $400 to $450 million per percentage point for the industry), the credit for exceeding the target should be based on the costs to the company (estimated to be $80 million per percentage point for the industry).

A system of credits should also be designed in such a way as to minimize any reduction in Annual Payments.

- Thus, we believe that any credits earned by tobacco companies should be offset first against surcharge payments that have been made by other companies.

- Only if total credits for any year exceed total surcharge payments should credits result in a reduction in Annual Payment obligations.[20]

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[20] Another way to avoid having credits reduce Annual Payments would be to establish the Look Back program as a system of transferable allocations. Each year, each tobacco company could be assigned an allocation based on its baseline share of the underage market and the targeted reduction in underage use for that year. Companies that exceed this target would have extra allocation units left over, which could then be transferred to companies that fall short of

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(6) Future Targets and Targets for Smokeless Tobacco.

We do not quarrel with the proposed settlement targets of 30%, 50%, and 60% reduction over the first ten years of the program.[21]

- These targets should be well within the reach of the tobacco companies.
- For example, our economic calculations suggest that if the price of a pack of cigarettes rises by $1.00, the economic disincentive to youth consumption may by itself allow the companies to reach the initial 30% target in year five.

But the targets should not be frozen at 60% for all years following year 10.

- Freezing the targets at 60% would mean that smoking by approximately 1.2 million adolescents (not accounting for population growth) is contemplated to continue indefinitely.
- Any legislation adopted should set an express goal of additional reduction in underage smoking over some reasonable interval of time.
- FDA should be authorized to adopt further incremental increases in targets for reductions underage smoking after year 10, with an ultimate goal of eliminating all but an incidental levels of underage smoking by year 20.

We also see no justification for setting targets for underage use of smokeless tobacco at substantially lower levels than the targets for underage use of cigarettes.

- Maintaining different targets for different tobacco products could result in underage use shifting from one nicotine delivery device to another.
- Smokeless tobacco products should therefore be subject to the same reduction targets, and the same general structure of incentives, as are cigarettes.

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[20] (...continued)
their target. Under such a system, the credit for exceeding the target would come in the form of a payment from another tobacco company, leaving the Annual Payments obligation untouched.

[21] These targets are not dissimilar to those endorsed by the Koop-Kessler Advisory Committee, supra at 5 n.3.

- To the extent that the lifetime social costs of using smokeless tobacco differ from the lifetime social costs of smoking, the surcharge payments for smokeless tobacco companies would be adjusted accordingly.

(7) The Role of the FDA.

In general we believe it is unwise for legislation adopting the Look Back surcharge to specify in great detail the methods of surveying for underage use.

- For example, it seems unwise to lock in by legislation the University of Michigan "Monitoring the Future" survey methodology. Better survey methods may be developed in the future that render this obsolete.

- Similarly, it seems inappropriate to specify whether youth smoking and reductions should be measured by daily smoking or monthly smoking. There are too many complications here to resolve by legislation. Moreover, a consensus that one method is better than another or that yet a third method is preferable may emerge over time.

- Furthermore, we believe that questions about whether targets should be expressed as percentages of the youth market or in terms of absolute number of underaged smokers should be left to agency determination.

- We agree with the proposed settlement that double counting of underage youths should be avoided. Again, however, this is the kind of technical problem that is best left to FDA resolution through rulemaking.

Rather than legislate the details of methodology, the legislation should resolve the major principles that would govern the Look Back program, and should leave the details to implementation of FDA through rulemaking. The major principles should be:

- There should be no automatic pass through of the surcharges in tobacco prices.

- The surcharge should not be tax deductible.

- The surcharge should be based on the discounted total lifetime social costs of underage smoking.

- The surcharge should not be subject to any cap, except perhaps for a cap equal to multiple percentage points of profit or each company's total net profits from domestic tobacco operations for the year.

- There should be no abatement for corporate compliance or good faith, although credits should be given to firms that exceed the targets.

- The targets should continue to progress after year ten and smokeless tobacco should be subject to the same targets as cigarettes.

VI. Funding of Public Health Programs.

The proposed settlement also provides for significant funding for various public health initiatives related to tobacco. Programs funded by the settlement include:

- A Presidential Commission to direct tobacco-related medical research.

- Programs directed by HHS to reduce smoking.

- Payment of FDA's enforcement costs under the agreement.

- State and local government community control efforts modeled after the ASSIST program.

- Research and development into methods for discouraging the use of tobacco.

- A public education program to discourage and de-glamorize tobacco products.

- Tobacco cessation programs.

- Compensation for events and teams that lose tobacco sponsorship.

The funds made available for these purposes range from $4.5 billion to $7.5 billion per year over the first ten years of the settlement. (A spread sheet showing the proposed allocation of Annual Payments over the first ten years is attached as Exhibit A to this Report).

- In addition, approximately $64 billion over the first ten years is not allocated by the settlement. Presumably, substantial portions of these funds are allocated to state governments for tobacco related health expenditures.

- Given the severe budget constraints that prevail in Washington and in most states, the generation of substantial sums of money for tobacco related research and education programs is clearly an important plus of the proposed settlement.

The monies allocated to these various programs vary widely. Moreover, there is no indication in the proposed settlement as to how the amounts were selected. Five of the grant programs are described as being "recommended by the Attorneys General for consideration by

the President and the Congress." This description suggests that the allocation of funds is open to adjustment.

We recommend four modifications in the allocation of funding under the proposed settlement.

- Funds should be allocated to a program to provide transitional relief to tobacco farmers who experience financial dislocation because of declining markets for tobacco leaf. One possibility would be a public program to purchase tobacco farmland or tobacco crop allotments from farmers who wish to exit the tobacco market.

- As discussed more fully below, funds should be allocated to international organizations devoted to achieving reductions in tobacco consumption worldwide.

- Funds should be allocated to support smoking cessation programs in health care settings. Studies suggest that intervention in the form of counseling by knowledgeable professionals may be cost-effective in assisting smokers to quit.[22]

- Funds should be allocated to support comprehensive school health education from pre-kindergarten to grade 12 in all U.S. school districts, designed in part to emphasize the dangers and the addictive potential of tobacco use.

More important than the initial allocation of funds, however, is the need to develop a governance mechanism for overseeing the expenditure of monies and to make changes in the allocation of funding over time.

- Ideally, of course, the funds would be allocated where they would do the most good.

- A thoughtful allocation requires a mechanism for selecting appropriate grant recipients, evaluating their performance, auditing the expenditure of monies, and so forth.

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[22] See Agency for Health Care Policy and Research, Smoking Cessation, Clinical Practice Guideline No. 18, U.S. Dept. of Health and Human Services AH CPR Pub. No. 96-0692 (April 1996); K. Fiscella and P. Franks, "Cost-Effectiveness of Transdermal Nicotine Patch as an Adjunct to Physicians' Smoking Cessation Counseling," 275 JAMA 1247-1251 (1996).

- Moreover, there should be a method for changing the allocation of funds over time, as experience and follow up studies show that greater benefits can be obtained from expenditures in some areas than in others.

The best entity to perform the functions of oversight and adjustment would seem to be the U.S. Department of Health and Human Services (HHS).

- The body that oversees the disbursement of these enormous sums of money should have a degree of political accountability. Thus, a private foundation or advisory board would not seem appropriate.

- On the other hand, decisions about administration of grants, evaluation of grant recipients, and changes in funding allocations (after an initial interval of, say, five years) should be informed, to the extent possible, by public health considerations rather than by interest group politics.

- An executive branch department such as HHS, which is subject to Presidential and Congressional oversight and yet insulated from direct political influence, strikes the best balance.

- We believe it would be appropriate for the legislation to require that HHS consult with one or more specialized institutions or commissions in establishing its oversight function and in making major decisions about reallocation of resources.

VII. Civil Liability.

Although the provisions of the proposed settlement regarding resolution of pending litigation and reducing the potential liability of tobacco companies from future litigation are complex, the public health implications of these provisions largely reduce to one overriding consideration: These provisions effectively eliminate the most significant deterrent effects from civil liability, and hence any future incentive for the industry to enter into further agreements expanding the regulatory regime that applies to tobacco. Once the settlement is approved, the tobacco companies will likely have no reason to return to the bargaining table.

(1) Limitations on Liability.

Perhaps the most important liability provisions are those that ban attorney general suits, class actions, joinder of multiple plaintiffs, consolidations, or actions by third party payors based on theories other than subrogation of individual claims.

- In the future, individual plaintiffs will have to go it alone against the tobacco companies.

- In the past, tobacco companies have been highly successful in defending against individual plaintiff suits. A major factor was their ability to concentrate heavy legal firepower defending these suits, often wearing down plaintiffs before trial. When the rare case went to trial, tobacco companies were able to persuade the jury that the individual plaintiff knew about the health risks of smoking and voluntarily accepted the risks of smoking. Until very recently, tobacco companies prevailed in each and every one of these trials.

- What forced the companies to the bargaining table was the emergence in recent years of class actions and attorney general suits. Class actions, in particular, focused attention on what the tobacco companies knew about their products, rather than on what individual smokers knew about the dangers of the products they chose to use.

- The proposed settlement, by requiring that all future suits be individual suits, allows the tobacco companies to return to a proven, successful litigation strategy.

The ban on class actions or other types of joinder is reinforced by the proposed settlement's limits on individual recoveries.

- A plaintiff's attorney will ordinarily take on a personal injury or products liability case only if it presents the prospect of a significant financial recovery.

- The proposed settlement eliminates punitive damages (for pre-settlement conduct), which would be a source of a large recovery in an individual suit.

- In addition, recovery is capped at $1 million per plaintiff if the annual industry cap (equal to 33% of the Base Amount) is exceeded.

- It appears that the proposed settlement extinguishes causes of action based on wrongful addiction or dependence.

- Finally, the proposed settlement preserves unchanged "applicable case law" under the Federal Cigarette Labeling and Advertising Act. This proviso presumably includes the Supreme Court's Cipollone decision,[23] which held that most causes of action based on failure to warn are preempted.

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[23] Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

- Given these serious constraints on recoveries, individual plaintiffs may face difficulties finding experienced attorneys to bring suits against tobacco companies.

As a final protection against significant liability, the proposed settlement puts an annual cap on total industry liability from all civil judgments equal to 33% of the Base Amount.

- This means total industry liability is capped at between $2 billion and $5 billion per year.

- Moreover, 80% of any settlements or judgments for any company may be credited against its Annual Payment obligations.

- The net effect is that the maximum additional industry financial exposure to civil liability (beyond the regularly scheduled Annual Payments) is from $400 million to $1 billion per year.

- This figure is not materially different from the estimated $600 million per year that the industry currently is spending on litigation in defense costs.[24]

Taken together, these changes eliminates the most significant threats of future civil liability.

(2) The Impact of Limitations on Liability.

One consequence of the limitations on liability is that future plaintiffs will have a substantially more difficult time obtaining at least some of the compensation they might have obtained (most likely as a members of class actions) under pre-settlement law.

- Some organizations will place significant weight on this factor. Consumer groups, public interest lawyers, and attorneys for smokers not currently in litigation probably will regard the reduced likelihood of compensation as a serious disadvantage of the proposed settlement.

- One difficulty with placing too much weight on lost compensation, however, is that up to now no private plaintiff has ever collected from a tobacco company.

- Consequently, the "loss" is a loss relative to a projected future state of litigation in which class actions, third party payor claims, etc. eventually start to produce recoveries or significant settlements from tobacco companies. Often losses of

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[24] "How Badly is Liggett Getting Burned?," Business Week, July 7, 1997.

this sort -- foregone opportunities -- are considered less troubling than deprivation of existing assets.

- In addition, some persons may question whether tobacco plaintiffs are entitled to compensation, given the widespread knowledge that smoking is dangerous.

From a public health perspective, we believe the consequence that deserves greater weight is the de facto elimination of any deterrent effect from civil liability. This will erase a powerful incentive for the tobacco companies to desist from socially harmful practices.

- If tobacco companies were to continue to face the threat of significant legal liability, it is difficult to predict their response. That would depend in part on which legal theories (if any) led to recoveries.

- Some of the responses might include more elaborate and emphatic warnings; changes in marketing; changes in products; withdrawing products from the market; raising prices (to cover liability costs); and withdrawing from the market altogether. In other words, the responses might parallel, and conceivably could go beyond, what is required by some of the regulations contained in the proposed settlement.

- In general, fear of civil liability is probably a more powerful stimulus to change in corporate behavior than is regulation. But it is also a highly uncertain stimulus with effects that are very difficult to predict in advance. Further, change through litigation could take years.

- We believe that the dramatic curtailment of the deterrent effect of civil liability for tobacco companies should be counted a major disadvantage of the proposed settlement.

There is another consequence of the effective elimination of the most significant threats of civil liability: It probably eliminates any further incentive on the part of the tobacco companies to cooperate in forging a public regulatory, research, and education program to solve the smoking problem.

- The primary reason the tobacco companies are at the bargaining table is that they apparently have become convinced that they face potentially catastrophic civil liability.

- In particular, it was the emergence of apparently viable class actions and the attorney general suits that made the difference. Suddenly the tobacco companies had to consider the possibility that they could follow the asbestos industry and the silicone breast implant industry into bankruptcy.

- The proposed settlement represents a critical opportunity to achieve fundamental structural changes in the regulatory treatment of tobacco -- and an opportunity that in all likelihood will never be presented again. If the present settlement is approved with the liability limitations in their present form, the tobacco industry is unlikely to be in a similarly vulnerable position in the future. This of course only underscores the importance of making sure the settlement is structured correctly.

VIII. Preserving The Integrity Of The Settlement.

This section briefly discusses some issues that concern the settlement as a whole.

(1) Nonsigning Tobacco Manufacturers.

The proposed settlement recognizes the important question of how nonsigning tobacco companies are to be treated. Of particular concern are foreign or new companies which could enter the market and, if not burdened by the Annual Payment obligations, might capture an increasing share of the market and possibly destabilize the agreement.

- The settlement agreement provides that nonsigning manufacturing companies will be subject to the same regulatory oversight and access restrictions as signing companies.

- It also provides that they will be subject to a "user fee" equal to the portion of the Annual Payments devoted to public health programs and federal and state enforcement of access restrictions that they would have paid if they had signed the agreement (III.C.bullet 2.).

- In addition, nonsigning must pay into an escrow account an amount equal to 150% of the Annual Payments that would be made by a signing company (minus the portion of the Annual Payments earmarked for public health payments and federal and state enforcement efforts). The escrow account is supposedly to satisfy potential judgments against such companies (which do not enjoy the limits on liability). If these companies are not found liable, however, the payments could sit in the escrow account, uncollected and gathering interest for 35 years.

- Thus, in immediate financial terms, the nonsigning companies must pay a substantially greater amount of money in order to participate in the market than the signing companies will pay.

- Finally, the proposed settlement opens up distributors and retailers who handle nonsigning companies to potential civil liability (distributors and retailers who handle signing company products are given full immunity from suits).

The provisions directed at nonsigning companies function as barriers to entry that lock in the current major manufacturing companies as a permanent oligopoly. For two reasons, this is undesirable from a public health perspective.

- One is that nonsigning companies may challenge these barriers on constitutional grounds, or possibly on the ground that they violate international trade agreements (such as GATT or NAFTA). The barriers thus increase the risk of legal challenges and potential invalidation of a key provision of the proposed settlement.

- Moreover, new entry could be desirable insofar as the new entrants seek to market products that have reduced health risks or that provide an effective substitute for the use of tobacco products.

Accordingly, the provisions dealing with nonsigning companies should be structured in such a way as to produce "a level playing field" between signing and nonsigning companies.

- Specifically, the provision establishing an escrow requirement should be amended to require posting of funds equal to 100% of the signing company Annual Payments, not 150%.

- Further, distributors and retailers who deal in the products of nonsigning manufacturing companies should be relieved of liability, as in the case of signing companies.

(2) Enforcement Of Consent Decrees.

As discussed above in connection with the advertising restrictions, the proposed settlement contemplates that many of its provisions will be incorporated both in legislation and in consent decrees.

- This is important because the consent decree provisions might survive if the legislation is struck down.

- Also, consent decrees have certain enforcement advantages -- a party can return to the court that entered the decree and get an injunction preventing the enjoined party from violating the decree, or an order holding a violating party in contempt.

The proposed settlement contains provisions indicating that the consent decrees will be entered in state court. This makes sense, given that the attorneys general brought the lawsuits being settled in state court. But it raises certain potential problems.

First, what about those states that do not join the agreement?

- The proposed settlement suggests that a contractual "protocol" will be adopted to handle this situation, but the precise mechanics of how this would work are not spelled out.

- It may be appropriate to condition the states' receipt of funding provided under the settlement upon their agreement to entering into binding consent decrees.

Second, how can the federal government enforce the consent decrees?

- We would prefer that the United States Department of Justice as well as state attorneys general have the power to enforce the consent decrees.

- It is not clear that the proposed settlement would provide for this. If not, a mechanism should be devised that would allow the federal government to become a party to the consent decrees, with full enforcement rights.

(3) Severability.

Whenever complicated regulatory legislation is enacted and constitutional challenges to portions of the legislation are a possibility, it is wise to attend to the "severability" question.

- If a provision of a statute that is struck down is severable, then invalidation of the provision does not affect the remainder of the statute.

- But if a provision of a statute that is struck down is not severable, then invalidation of the provision means the whole statute falls.

A strong severability clause should be included in the legislation, making clear that if any provision is declared invalid, the constitutionality of the balance of the statute is not affected.

(4) Global Extension.

International issues are not covered by the proposed settlement. A truly comprehensive discussion of tobacco control policy would address the rapid growth in tobacco use around the world, with especially alarming increases in developing countries. To some extent, these

concerns can be addressed within the framework of the settlement. In other respects they are best approached through other initiatives.

Steps that can be taken within the framework of the settlement include:

- Allocation of funds from the Public Health Trust or other appropriate sections of the settlement to the World Health Organization (WHO), to be dedicated to the development, adoption, and enforcement of the WHO Framework Tobacco Control Convention, surveillance systems to monitor international morbidity and mortality, and other tobacco control initiatives.

- Allocation of funds from the settlement for federal agency use in international tobacco control efforts.

Other initiatives apart from the settlement by the federal government might include:

- An Executive Order to all appropriate federal agencies to promote actively the adoption of U.S. domestic tobacco control standards as minimum policies throughout the world. Tools for achieving this objective would include export initiatives, Aid for International Development programs, and other communications and information programs. An international summit of health ministers should be convened in 1998 to discuss tobacco control issues, with a follow-up meeting at the World Conference on Tobacco and Health in the year 2000.

- An Executive Order forbidding the U.S. Trade Representative, the Department of Commerce, U.S. embassies, or other government agencies from interfering in any efforts by foreign national governments to curb tobacco use.

- An Executive Order making all U.S. government facilities, worldwide, smoke free.

- Imposition of penalties on U.S. companies that participate in or support international tobacco smuggling, including reintroduction to the U.S. of cigarettes made for export.

The American Medical Association will support the above initiatives in international tobacco use prevention and control, and will work for their implementation with the international medical and public health community, including the World Medical Association.

IX. Recommendations.

The proposed settlement is a promising beginning. It lays out an internally coherent system of regulatory reform, financial incentives, and relief from civil liability. The overall design of the settlement establishes a framework that can be used to achieve real, permanent, and major public health benefits. On the other hand, certain critical changes must be made in portions of the proposed settlement if this goal is to be realized.

(1) Essential Changes.

Two changes in particular are essential if the settlement is to achieve the public health goals we have set out.

The FDA must be given the same authority over tobacco products that it has over other "drugs" and "devices" under the Food, Drug and Cosmetic Act -- with the sole exception of the 12 year moratorium on taking action to implement a prohibition of traditional tobacco products or the elimination of nicotine from tobacco products.

This modification should be implemented through the following revisions to the proposed settlement, or their equivalent:

- There should be a constructional principle indicating that FDA has full authority over all tobacco products and other nicotine delivery devices unless a specific exception is expressly set forth in the legislation.

- The settlement should be clarified by eliminating any language that suggests that FDA authority to regulate tobacco products is limited in ways other than the 12 year moratorium.

- FDA should be permitted to use the same procedures, and its decisions should be subject to the same standard of review, that generally apply under the Food, Drug and Cosmetic Act.

- The definition of "tobacco product" should be clarified to include pipe tobacco, cigars, and any other tobacco product.

The Look Back surcharge program must be redesigned so as to provide significant financial incentives for each tobacco company to achieve the targets for reduction in underage tobacco use set forth in the proposed settlement.

This modification should be implemented through the following revisions to the proposed settlement, or their equivalent:

- The Look Back surcharge payments should not be subject to the automatic pass through and should not be tax deductible.

- The Look Back surcharge payments should be assessed against each individual company based on reductions in underage use achieved by that company. They should not be assessed on the basis of collective industry responsibility.

- The Look Back surcharge payments should be based on the discounted present value of the lifetime social costs of tobacco use, not restitution of profits.

- The $2 billion cap on annual surcharge payments should be eliminated. Any cap should be based on a multiple of company profits from underage use or on total company profits in the domestic market.

- Tobacco companies that exceed the targets should be given a financial credit. There should be no abatement for compliance with regulations and corporate good faith.

(2) **Strongly Recommended Changes.**

In addition to the foregoing essential changes, we strongly recommend the following additional changes in the proposed settlement.

- The price of cigarettes should be targeted to rise by about $1.00 per pack, as opposed to the $0.62 per pack projected under the proposed settlement. This can be accomplished by an increase in the cigarette excise tax, by upward adjustments in the Annual Payments, or by modifications in the tax treatment of existing Annual Payments.

- FDA should have authority progressively to tighten the targets of the Look Back program after the ten year period addressed by the proposed settlement, with an ultimate goal of reducing underage tobacco use to incidental levels.

- The preemptive effect of federal youth access restrictions should be narrowed and clarified so that states and local governments may impose civil sanctions on tobacco retailers beyond the federal minimum.

- The preemptive effect of federal advertising restrictions should be narrowed and clarified so that states and local governments may regulate local advertising and marketing and may impose counter-advertising requirements on tobacco companies.

- The restriction on advertising to tombstone-only format should be extended to all publications.

- A federal agency (such as HHS) should be given overall responsibility for disbursement of the Public Health component of the Annual Payments, including oversight of grant recipients and authority to make adjustments in allocations in future years.

- The provisions regarding nonsigning companies should be modified so as to avoid erecting unnecessary barriers to new entry.

- The Look Back program should have targets for reduction of underage use of smokeless tobacco identical to the targets for reduction in underage smoking.

(3) Recommended Changes.

We have throughout this document recommended a number of other clarifications or refinements in the proposed settlement. These include the following:

- The prohibition on sponsorship should be clarified to preclude tobacco company sponsorship of computer software, Internet, or video programming that glamorizes the use of tobacco.

- The flow of funds from tobacco companies to the states should be structured so that federal standards for state licensing statutes and enforcement programs can be adopted as conditions attached to federal funding.

- States should be expressly permitted to make it a criminal or civil offense for any person, not just a retailer, to sell tobacco products to a minor.

- Federal enclaves and facilities, including military bases and hospitals, should be required to comply with state and local regulations regarding access to tobacco products, and tobacco sales at federal facilities should be subject to federal taxes equal to those that prevail in the local area.

- The antitrust exemption for collective price setting by tobacco companies should be clarified to prohibit companies from raising prices to profit maximizing levels.

- Portions of the Public Health component of the Annual Payments should be allocated to (a) providing transitional relief to displaced tobacco farmers; (b) providing funds to the World Health Organization for the development of a Framework Tobacco Control Convention and other international tobacco control

initiatives, and to federal agencies for use in international tobacco control efforts; (c) providing funds to support tobacco cessation programs in health care settings; and (d) providing funds for mandated comprehensive school health education focusing in part on the dangers of tobacco use.

- Distribution of funds to states should be conditioned on each state, including states that have not sued the tobacco companies, entering into a consent decree embodying the provisions of the settlement.

- The federal government should become a party to the consent decrees, with full enforcement power.

- The legislation implementing the settlement should include a strong severability clause.

If the changes that we have advocated or equivalent changes are adopted by Congress, the Task Force believes that the proposed settlement would be a major turning point in the life-or-death struggle to reduce tobacco use. The American Medical Association pledges to devote its resources toward securing the adoption of these changes. The AMA also stands ready to work in any constructive capacity with the parties to the settlement, members of Congress, and the Administration in order to realize what could be a landmark achievement.

ORGANIZATIONAL COMPARISONS

FDA

AMERICAN MEDICAL ASSOCIATION

The FDA must be given the same authority over tobacco products that it has over other "drugs" and "devices" under the Food, Drug and Cosmetics Act, with the sole exception of the 12-year moratorium on the prohibition of traditional tobacco products or the elimination of nicotine from tobacco products.

- There should be a constructional principle indicating that FDA has full authority over all tobacco products and other nicotine delivery devices unless a specific exception is expressly set forth in the legislation.
- The settlement should be clarified by eliminating any language that suggests that FDA authority to regulate tobacco products is limited in ways other than the 12-year moratorium.
- FDA should be permitted to use the same procedures, and its decisions should be subject to the same standard of review that generally apply under the Food, Drug and Cosmetic Act.
- The definition of "tobacco product" should be clarified to include pipe tobacco, cigars, and any other tobacco product.

AMERICAN CANCER SOCIETY

The FDA 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

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

No changes to the FDA's current authority or limits on future authority are acceptable. FDA's hands should not be tied with increased regulatory "hoops and ladders." Nicotine is the reason people become addicted to cigarettes and it must be cut as soon as practicable.

- Delete 12-year provision

AMERICAN HEART ASSOCIATION

FDA must be guaranteed complete authority over tobacco products, including nicotine, and must be provided appropriate resources to carry out its regulatory role.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

The FDA must have the authority to regulate the manufacture, sale, labeling, distribution, and marketing of tobacco products.

AMERICAN ACADEMY OF PEDIATRICS

FDA should be able to modify the amount of nicotine and other harmful ingredients in tobacco products without being exposed to complicated regulatory, judicial, and legislative maneuvers.

ORGANIZATIONAL COMPARISONS

LOOK BACK

AMERICAN MEDICAL ASSOCIATION

The Look Back surcharge program must be given real teeth. If the tobacco industry is to be relieved of any significant civil liability and if FDA jurisdiction is to be subject to a 12-year moratorium on nicotine elimination, it is essential that financial incentives be put in place that will guarantee significant reductions in underage smoking and smokeless tobacco.

- Look Back surcharge payments should not be subject to the automatic pass through and should not be tax deductible.
- Look Back surcharge payments should be assessed against each individual company based on reductions in underage use achieved by that company. They should not be assessed on the basis of collective industry responsibility.
- Look Back surcharge payments should be based on the discounted present value of the lifetime social costs of tobacco use, not restitution of profits.
- The $2-Billion cap on annual surcharge payments should be eliminated. Any cap should be based on company profits from underage use or on total company profits in the domestic market.

Credit for compliance with regulations and corporate good faith should be replaced by rewards for companies that exceed the targets in any given year.

AMERICAN CANCER SOCIETY

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.

Raise the federal tobacco excise tax to $2 per pack of cigarettes with a proportional increase on smokeless tobacco products.

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

The penalty is not strong enough and should be made company-specific, so no company would be tempted to do less than its share. Nonfinancial actions also should be taken, including "plain packaging" and a ban on al advertising by the offending company.

AMERICAN HEART ASSOCIATION

The penalties outlined in the settlement should serve as a floor for Congress in determining how much the industry should pay if youth smoking does not decrease by specified amounts.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

The industry must be held accountable for meeting targets for youth reduction in tobacco use, starting in year 2 and increasing every year thereafter. Strong financial penalties and/or other regulatory sanctions must guarantee the accountability of the industry's compliance to such objectives.

AMERICAN ACADEMY OF PEDIATRICS

The penalties/enforcement measures for reducing children's tobacco use are not sufficient. The academy supports the recommendation by the Advisory Committee on Tobacco Policy and Public Health.

ORGANIZATIONAL COMPARISONS

TOBACCO PRICING

AMERICAN MEDICAL ASSOCIATION

The price of cigarettes should be targeted to rise by $1 per pack, as opposed to the $.62 per pack projected under the proposed settlement. This can be accomplished by an increase in the cigarette excise tax, by upward adjustments in the Annual Payments, or by modifications in the tax treatment of existing annual payments.

AMERICAN CANCER SOCIETY

Raise the federal tobacco excise tax to $2 per pack of cigarettes with a proportional increase on smokeless tobacco products.

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

Increase excise taxes

AMERICAN HEART ASSOCIATION

The settlement should not preclude the use of tax policy to further decrease consumption of tobacco products, particularly among the nation's youth. Aggressive enactment of federal and state tobacco excise taxes must be maintained

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

NO POSITION

AMERICAN ACADEMY OF PEDIATRICS

NO POSITION

ORGANIZATIONAL COMPARISONS

FUNDS DISBURSEMENT

AMERICAN MEDICAL ASSOCIATION	AMERICAN CANCER SOCIETY	AMERICAN LUNG ASSOCIATION AMERICAN THORACIC SOCIETY
A federal agency (such as HHS) should be given overall responsibility for disbursement of the Public Health component of the Annual Payments, including oversight of grant recipients and authority to make adjustments in allocations in future years.	NO POSITION	NO POSITION

AMERICAN HEART ASSOCIATION	AMERICAN COLLEGE OF PREVENTIVE MEDICINE	AMERICAN ACADEMY OF PEDIATRICS
Funds should be handled by organizations independent of tobacco industry influence.	NO POSITION	NO POSITION

ORGANIZATIONAL COMPARISONS

PREEMPTION

AMERICAN MEDICAL ASSOCIATION

The preemptive effect of federal youth access restrictions should be narrowed and clarified so that states and local governments may impose civil sanctions on tobacco retailers beyond the federal minimum.

AMERICAN CANCER SOCIETY

States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws

AMERICAN HEART ASSOCIATION

Settlement must not preempt the initiation, adoption and/or enforcement of state or local laws that are more comprehensive/severe in reducing sales, marketing, and use of tobacco products, and restricting smoking in public places.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

NO POSITION

AMERICAN ACADEMY OF PEDIATRICS

NO POSITION

ORGANIZATIONAL COMPARISONS

ADVERTISING/PROMOTION

AMERICAN MEDICAL ASSOCIATION

The preemptive effect of federal advertising restrictions should be narrowed and clarified so that states and local governments may regulate local advertising and marketing and may impose counter-advertising requirements on tobacco companies.

Only black and white "tombstone" advertising should be permitted.

AMERICAN CANCER SOCIETY

NO POSITION

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

Advertising must be more comprehensively restricted because tobacco companies will find creative ways to get around piecemeal restrictions to market their products, as has been done in other countries trying this approach. Restriction examples include: publications with more than 15% youth readers; no ads, marketing or promotion campaigns; other publications black/white depiction of product and package only; and an end to payments to entertainment/sports figures to smoke in "public" or in the course of their professions.

AMERICAN HEART ASSOCIATION

NO POSITION

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

Advertising and promotion restrictions must be increased to provide for a total advertising ban covering all tobacco products.

AMERICAN ACADEMY OF PEDIATRICS

Supports a ban on all tobacco product advertising.

AMA RECOMMENDATIONS
PROPOSED TOBACCO SETTLEMENT

FDA	LOOK BACK	TOBACCO PRICING	FUNDS DISBURSEMENT	PREEMPTION	ADVERTISING/ PROMOTION
• Same authority over tobacco products that it has over other "drugs" and "devices" • Same regulatory process applies as with other drugs/devices • 12-year moratorium on complete ban of nicotine; interim nicotine restrictions allowed	• Provides significant financial incentives for each tobacco company to achieve cuts in youth smoking • Penalties based on lifetime social cost of tobacco use* • Penalties not tax deductible • No annual cap • No abatement; rewards for companies to exceed target • Assessments against individual companies	• Increase price of cigarettes by $1 per pack -- Increase tax, or -- Increase annual industry payment, or -- Modify tax deductibility of annual payment	• A governmental agency should have responsibility for the public health aspect of funding, including asset allocation and expenditures	• States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws	• Only black/white "tombstone" advertising should be permitted • State and local governments should be permitted to regulate advertising and marketing

ORGANIZATIONAL COMPARISONS

PROVISION	AMA	ACS	ALA	AHA	ACPM	AAP
TOBACCO PRICING	• Increase price of cigarettes by $1 per pack -- Increase tax, or -- increase annual industry payment, or -- Modify tax deductibility of annual payment	• Raise federal excise tax to $2 per pack/raise smokeless tobacco tax proportionally	• Increase excise taxes	• Increase excise taxes	NO POSITION	NO POSITION
FUNDS DISBURSEMENT	• A governmental agency should have responsibility for the public health aspect of funding, including asset allocation and expenditures	NO POSITION	NO POSITION	• Funds should be handled by organizations independent of tobacco industry influence	NO POSITION	NO POSITION
PREEMPTION	• States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws	• States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws	• States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws	• No preemption of sales, marketing, tobacco use laws or clean indoor air restrictions	NO POSITION	NO POSITION
ADVERTISING/ PROMOTION	• Only black/white "tombstone" advertising should be permitted • State and local governments should be permitted to regulate advertising and marketing	NO POSITION	• Comprehensive advertising and marketing restrictions • Black/white depiction of product package only	• NO POSITION	• Total ban on all tobacco product advertising and promotion	• Total ban on all tobacco product advertising and promotion

AMA = American Medical Associat n

ACS = American Cancer Society

ALA = American Lung Association

AHA = American Heart Associat

ACPM = American College of Preventiv Medicine

AAP = American Academy of Pediatrics

ORGANIZATIONAL COMPARISONS

PROVISION	AMA	ACS	ALA	AHA	ACPM	AAP
FDA	• Same authority over tobacco products that it has over other "drugs" and "devices" • Same regulatory process applies as with other drugs/devices • 12-year moratorium on complete ban of nicotine; interim nicotine restrictions allowed	• Maintain FDA authority over tobacco • No increased regulatory burdens • Delete 12-year provision	• No changes to FDA authority • No increased regulatory burdens • Delete 12-year provision	• Complete authority over tobacco products, including nicotine regulation	• Authority to regulate the manufacture, sale, labeling, distribution, and marketing of tobacco products	• Authority to modify nicotine and other cigarette ingredients without increased regulatory burden
LOOK BACK	• Provides significant financial incentives for each tobacco company to achieve cuts in youth smoking • Penalties based on lifetime social cost of tobacco use* • Penalties not tax deductible • No annual cap • No rewards for companies that exceed target • Assessments against individual companies	• Provide economic incentives to ensure industry compliance • No annual cap or rebate • Assessments against individual companies	• Increased financial penalty • Consider non-financial penalties • Assessments against individual companies	• Current penalties as a "floor" for future action	• Strengthen financial penalties • Consider non-financial sanctions • Begin penalties in year 2 • Not tax deductible	• Strengthen penalties/enforcement • Company specific penalties • Begin penalties in year 2