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

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ORGANIZATIONAL COMPARISONS

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AMERICAN COLLEGE OF PREVENTIVE MEDICINE

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AMERICAN ACADEMY OF PEDIATRICS

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ORGANIZATIONAL COMPARISONS

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AMERICAN HEART ASSOCIATION

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DPC Draft 8/11/97

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
Overall Position	Congress should reject the settlement and legislate a strong tobacco policy. It does not need the industry's help or permission to do this.	Settlement is a landmark effort that would generate far more $ for public health activities than Congress would ever appropriate. Preferable to the uncertainty and delay of litigation.	Settlement is a great start for providing revenues for public health programs. No single piece of federal legislation will solve America's tobacco problem.	Settlement is not perfect but could help to significantly reduce tobacco use.	Settlement as written will not protect the public health. Industry can manipulate gaping loopholes.
Priority Issues	-5 Goals: 1. unhampered FDA regulation of nicotine 2. prohibition of industry efforts to target kids 3. stiff penalties for targeting kids 4. smoke-free public places 5. excise tax to fund education and cessation programs -Increase of at least $2 per pack	-Strengthen FDA jurisdiction -Increase Look Back penalties fivefold -Increase of $1 per pack -Make smokeless tobacco Look Back targets identical to smoking targets -Allow FDA to tighten Look Back targets after 10 years -Expand ad restrictions to allow only black/white "tombstone" ads for all publications -Do not preempt stricter state sanctions on retailers	-Expand authority of FDA -FDA must have all documents relevant to the public health. -Increase settlement payments to produce at least a $2 per pack increase -No tax-deductibility -Increase Look Back penalties	-Complete authority for FDA over tobacco products and nicotine -No immunity for past criminal wrongdoing -Harsher Look Back penalties -Full and open disclosure of all documents that relate to health issues -Prevent industry from escaping obligations and liability through bankruptcy	-No changes or limits on FDA authority -No immunity or limits on industry's liability -Comprehensive ad restrictions that the industry can't get around creatively -Much higher Look Back penalties -Zero tolerance for ETS -Disclosure of documents shielded by attorney-client privilege -A morally acceptable export policy -No tax-deductibility
FDA Regulation	-Make explicit FDA's unlimited authority to regulate and phase out nicotine and remove other ingredients that contribute to the initiation of and dependence on tobacco products -Time limits or moratoriums on FDA activity should be flexible to accommodate advances in science, information, and health policy.	-FDA should have same authority as for drugs and devices. -FDA should be able to use same procedures (notice and comment) and standard of review (arbitrary and capricious) that generally apply under FDCA. -12-year moratorium on complete ban of nicotine; allow interim restrictions.	-Authority for FDA to develop tough performance standards that aim to reduce or eliminate any constituent, including nicotine and that apply from the effective date of the act -No formal rulemaking -Eliminate heightened standards of proof and FDA's black market obligation	-Complete authority over tobacco products and nicotine -Eliminate excessive bureaucracy -More resources -Concerned about formal rulemaking and black market requirements	-No changes to FDA authority - No formal rulemaking requirement -No obligation to prove unlikelihood of black market - Industry should not be allowed to designate any ingredient a confidential trade secret.

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
Look Back	-Adopt stronger targets: 15%-30% from years 1-5, and then 40%-65% from years 5-10. -No cap on penalties for failure -Increase penalties: if industry misses target by 5 points, it should pay 5 times the sanction -Assess compliance and penalties on a company-by-company basis	-No automatic pass through -No tax deductibility -Penalties should be assessed against each individual company based on its own reductions in underage use -Increase penalties from $80 million to $400-$450 million to force industry to internalize social costs of underage use -Eliminate $2 billion cap -Eliminate 75% rebate; add a $80 million credit for each extra percentage point of reduction -Give FDA authority to tighten targets after 10 years	-Increase penalties -Eliminate 75% rebate -Eliminate $2 billion cap -Reduction targets for smokeless tobacco should be the same as for cigarettes, because its use among teenage boys has outpaced their use of cigarettes.	Penalties in the settlement should establish the floor--make them more severe. Amounts should be adjusted annually to reflect the most current data on teen smoking.	-Individual company accountability for reduction -Additional nonfinancial penalties like more ad restrictions -Define "reasonable available measures" in detail, so industry can't get the 75% rebate easily
Document Disclosure	Industry must disclose all documents that: -reveal public relations, advertising, marketing, promotion, and political activities -are improperly shielded by attorney-client privilege -reveal all technical and health/safety data -indicate industry strategies for targeting kids and minorities -show health effects of ETS	No recommendation. Dr. Lonnie Bristow has said that the 3-judge panel procedure is acceptable.	-Streamline 3-judge panel procedure -Industry must show why a document should not be disclosed -FDA must have all information relevant to the public health and the development of reduced risk tobacco products.	Full and open disclosure of all documents that relate to health issues	Streamline/eliminate overly time-consuming, bureaucratic review mechanisms like the document-by-document review of privileged records by industry lawyers.

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
Immunity	Congress does not know enough of the industry's secrets to grant it any immunity. Preserve all avenues of litigation, both civil and criminal.	Immunity to class action suits and punitive damages is a major drawback of the settlement. Class actions draw attention to industry deceit, whereas individual suits focus on plaintiff's personal responsibility. Punitives are the major source of large recovery for plaintiffs--without them, there is no incentive for individual suits. Free of the fear of liability, industry won't change its bad behavior.	No recommendation.	No immunity to either companies or their agents for past criminal wrongdoing. No statement regarding bans on class actions or punitive damages.	-Adamantly opposes any immunity or limits on the industry's future liability -No cap on damages -No ban on class actions -No limits on punitive damages -Requiring public to accommodate corporate wrongdoing sets a dangerous precedent.
Size of Payments/ Price per Pack	-Excise taxes should be dramatically increased and should be indexed to inflation (studies show $2 per pack or more may be appropriate). -Financial punishments should not be considered ordinary business expenses and tax deductible -Demand more money--the industry will boom under the current settlement as it is already targeting 18-24 year-olds.	Increase of at least $1 per pack is necessary-- would result in a 15% reduction in overall consumption and a 33% in youth consumption.	-Payments are too small--either the payments or excise tax should produce a $2 increase in price per pack. -Tax deductibility of payments makes things too easy for industry and decreases federal revenues.	Aggressive enatment of federal and state excise taxes must be maintained.	Tax provisions that make every penny tax-deductible make things too easy for the industry.

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
ETS	Ban smoking in: -all work sites -all places of public assembly -outdoor areas where people assemble, like service lines, arenas -schools- inside and outside -all forms of public transportation, including flights going in and out of U.S. -all federal workplaces, including branches of military and VA hospitals	No recommendation. By enacting the Smoke-Free Environment Act of 1993, the settlement would achieve more than would stand alone legislation.	No recommendation. It is good that the provision would not preempt more stringent state or local laws restricting smoking in public places.	No preemption of stronger local and state policies. OSHA standards are the minimum that must be met.	Settlement should protect restaurant, bar, and hospitality workers who are most at risk for passive smoking disease. Advocates zero tolerance for tobacco smoke.
Farmers	-Blue-ribbon panel should recommend short- and long-term strategies to reduce tobacco states' and communities' dependence on the crop. -Industry should finance an economic assistance and development fund to help tobacco farmers and non-farm industry workers find alternatives. -More settlement funds should go to farmers and less to trial lawyers.	Congress should use settlement funds to establish a public program to purchase tobacco farmland or tobacco crop allotments from farmers who want to leave the tobacco market.	No recommendation.	Set aside a portion of excise taxes to provide tobacco-producing communities with economic development assistance and opportunities for crop diversification.	No recommendation.

DPC Draft 8/11/97

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
Overall Position	Congress should reject the settlement and legislate a strong tobacco policy. It does not need the industry's help or permission to do this.	Settlement is a landmark effort that would generate far more $ for public health activities than Congress would ever appropriate. Preferable to the uncertainty and delay of litigation.	Settlement is a great start for providing revenues for public health programs. No single piece of federal legislation will solve America's tobacco problem.	Settlement is not perfect but could help to significantly reduce tobacco use.	Settlement as written will not protect the public health. Industry can manipulate gaping loopholes.
Priority Issues	-5 Goals: 1. unhampered FDA regulation of nicotine 2. prohibition of industry efforts to target kids 3. stiff penalties for targeting kids 4. smoke-free public places 5. excise tax to fund education and cessation programs -Increase of at least $2 per pack	-Strengthen FDA jurisdiction -Increase Look Back penalties fivefold -Increase of $1 per pack -Make smokeless tobacco Look Back targets identical to smoking targets -Allow FDA to tighten Look Back targets after 10 years -Expand ad restrictions to allow only black/white "tombstone" ads for all publications -Do not preempt stricter state sanctions on retailers	-Expand authority of FDA -FDA must have all documents relevant to the public health. -Increase settlement payments to produce at least a $2 per pack increase -No tax-deductibility -Increase Look Back penalties	-Complete authority for FDA over tobacco products and nicotine -No immunity for past criminal wrongdoing -Harsher Look Back penalties -Full and open disclosure of all documents that relate to health issues -Prevent industry from escaping obligations and liability through bankruptcy	-No changes or limits on FDA authority -No immunity or limits on industry's liability -Comprehensive ad restrictions that the industry can't get around creatively -Much higher Look Back penalties -Zero tolerance for ETS -Disclosure of documents shielded by attorney-client privilege -A morally acceptable export policy -No tax-deductibility
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Size of Payments/ Price per Pack	-Excise taxes should be dramatically increased and should be indexed to inflation (studies show $2 per pack or more may be appropriate). -Financial punishments should not be considered ordinary business expenses and tax deductible -Demand more money--the industry will boom under the current settlement as it is already targeting 18-24 year-olds.	Increase of at least $1 per pack is necessary-- would result in a 15% reduction in overall consumption and a 33% in youth consumption.	-Payments are too small--either the payments or excise tax should produce a $2 increase in price per pack. -Tax deductibility of payments makes things too easy for industry and decreases federal revenues.	Aggressive enatment of federal and state excise taxes must be maintained.	Tax provisions that make every penny tax-deductible make things too easy for the industry.

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
ETS	Ban smoking in: -all work sites -all places of public assembly -outdoor areas where people assemble, like service lines, arenas -schools- inside and outside -all forms of public transportation, including flights going in and out of U.S. -all federal workplaces, including branches of military and VA hospitals	No recommendation. By enacting the Smoke-Free Environment Act of 1993, the settlement would achieve more than would stand alone legislation.	No recommendation. It is good that the provision would not preempt more stringent state or local laws restricting smoking in public places.	No preemption of stronger local and state policies. OSHA standards are the minimum that must be met.	Settlement should protect restaurant, bar, and hospitality workers who are most at risk for passive smoking disease. Advocates zero tolerance for tobacco smoke.
Farmers	-Blue-ribbon panel should recommend short- and long-term strategies to reduce tobacco states' and communities' dependence on the crop. -Industry should finance an economic assistance and development fund to help tobacco farmers and non-farm industry workers find alternatives. -More settlement funds should go to farmers and less to trial lawyers.	Congress should use settlement funds to establish a public program to purchase tobacco farmland or tobacco crop allotments from farmers who want to leave the tobacco market.	No recommendation.	Set aside a portion of excise taxes to provide tobacco-producing communities with economic development assistance and opportunities for crop diversification.	No recommendation.