

REPORT OF THE *KESSLER-KOOP* ADVISORY COMMITTEE ON TOBACCO POLICY AND PUBLIC HEALTH RELEASED JULY 9, 1997

Introduction by the Co-Chairs

On May 22, 1997, a bipartisan group of Members of Congress asked us to convene a committee on national tobacco policy. In response to this request, we formed the panel that has met as the Advisory Committee on Tobacco Policy and Public Health. This Committee is composed of representatives of some of the major public health groups that have been leaders in the debate on tobacco control. The selection of organizations to be represented was an especially difficult task, inasmuch as so many highly qualified groups with great expertise are involved in tobacco control; nevertheless, in order to make the Committee of manageable size, we made hard choices to limit the number of members and urged them to consult with a wide range of other organizations and experts.

The Committee has as its mission the development of a comprehensive and rational public health policy toward tobacco, containing clear goals and principles, in order to provide a benchmark against which future public and private activities can be measured.

The Committee has met three times, each time in open session, on June 5, June 18, and June 25. To conduct its work, the Committee resolved itself into five task forces on overlapping topics:

- Regulation of Nicotine and Tobacco Products (Chair: American Cancer Society)
- Youth and Tobacco (Chair: American Academy of Pediatrics)
- Performance Objectives Subgroup (Chair: Partnership for Prevention)
- Current Users of Tobacco Products (Chair: American Medical Association)
- Environmental Tobacco Smoke (Chair: American Lung Association)
- Future of the Tobacco Industry and Tobacco Control Efforts (Chair: Advocacy Institute)

These task forces conferred independently and made their preliminary reports to the Committee. Each report was discussed in open session and amendments were made. Revised reports were developed and summarized.

We believe that this final report speaks loudly for itself, but it is perhaps appropriate for us to note here what this report does not speak to. This is not a report on past actions of the tobacco industry or on the harm that it has done. It is not intended to recommend how tobacco litigation or compensation programs for past injury should be handled. It is

how tobacco litigation or compensation programs for past injury should be handled. It is not a report on liability for the past.

Rather, in keeping with the Congressional charge, this is a blueprint for the future of tobacco policy and public health. It is neither incremental nor utopian. The plans outlined are ambitious but they can be achieved within a short time.

Most of all, this report is a document intended to look forward, and to move the Nation from its past injuries to future good health. Its recommendations are to ensure complete ability for the FDA to regulate nicotine and tobacco products, to prevent our children from starting to smoke, to treat those already addicted to tobacco, and to protect nonsmokers from involuntary exposure to smoke. These are the goals for which all new policy should aim. Any approach that fails these goals fails the Nation and fails the future.

We fully recognize that there are billions of dollars at stake here in hospital bills, compensation, and liability costs. While these are important issues, we believe that this debate about the past should not distract us from solid plans for the future. Not one of those compensatory dollars will be well spent if our children repeat their elders' mistakes, if adults continue their addiction, or if we all have smoke in our faces. As the national debate about tobacco continues, we urge all sides to keep their eyes clearly on this extraordinary opportunity for change.

What follows is a summary of the major recommendations of each of the task forces. An appendix has been included that contains the full final report of each of the task forces.

We want to thank and acknowledge our colleagues who have joined us for this daunting task in such a brief amount of time. We appreciate the expertise, commitment, and labor that have been contributed. We are confident that our work together will change the debate for the better.

C. Everett Koop, M.D., Sc.D.

David A. Kessler, M.D.

Summary of Major Recommendations of the Task Force on the Regulation of Nicotine and Tobacco Products

BACKGROUND

"[N]icotine in cigarettes and smokeless tobacco has the same pharmacological effects as other drugs that FDA has traditionally regulated." [61 Fed. Reg. 168, 44661 (1996)] Indeed, it is acknowledged that nicotine is extremely addictive and that "the vast majority of people who use nicotine-containing cigarettes and smokeless tobacco do so to satisfy their craving for the pharmacological effects of nicotine; that is, to satisfy their drug-dependence or addiction." [Id. at 44636 (comments of the American Heart Association, the American Lung Association, and the American Cancer Society).] Many would argue, therefore, that the regulation of nicotine and its delivery is itself the most essential element of tobacco control activities.

Other components of tobacco smoke are also toxic. The tar, carbon monoxide, and additives contained therein are dangerous to the health of those using tobacco and those around them.

RECOMMENDATIONS

Regulatory Policy

- FDA should continue to have authority to regulate all areas of nicotine, as well as other constituents and ingredients, and that authority should be made completely explicit.
- FDA should continue to have the authority to phase out nicotine and remove ingredients that contribute to the initiation of smoking and dependence on cigarettes and other tobacco products (including smokeless tobacco, pipes, cigars, and roll-your-own tobacco), and that authority should be made completely explicit.
- There should be no limitations on or special exceptions to FDA authority to regulate nicotine, other constituents, and ingredients of tobacco products and such a no-limitations policy should be made completely explicit.
- The FDA should continue to have authority to regulate further nicotine, other constituents, and ingredients as the evidence suggests. The best science, information, and health policy (and not an arbitrary deadline) should drive FDA regulatory timing and that authority should be made completely explicit.
- The FDA should have the authority to test nicotine levels by brand, based on the best science and that authority should be made completely explicit.
- Regulation of non-tobacco nicotine delivery devices (e.g., nicotine patches, nicotine gum, nicotine inhalers, etc.) should be done in a manner that does not make the development and sale of less hazardous systems difficult and that encourages maximum overall reduction in disease.

Research Policy

- FDA should have the authority and funding to conduct research on nicotine and other components of tobacco products.
- International exchange and scientific conferences on nicotine and other components of tobacco products should be convened among private industry researchers and public researchers (such as those from the FDA, the CDC, the NIH, and the WHO).
- Research should be conducted on the effects of nicotine in children and adolescents.

Fiscal Policy

- FDA should be adequately funded to carry out its regulatory, enforcement, public education, and research activities.

Summary of Major Recommendations of the Task Force on Youth and Tobacco

BACKGROUND

More than 90 percent of people who will ever smoke on a regular basis begin doing so prior to the age of 19. Each day, some 3,000 children take up the habit; the average age at which they begin is approximately 12-1/2, although many decide to smoke earlier if they are able. While these children start to use tobacco for a variety of reasons, very quickly they become addicted to the nicotine present in the product, and studies show clearly that children have just as difficult a time quitting as do adults.

There are a number of reasons why children begin to use tobacco. Among these are the remarkably effective advertising and promotion by the tobacco industry and, for many young people, perceived benefits from the use of tobacco, be they adult privileges, appealing images, or the opportunity for rebelliousness.

RECOMMENDATIONS

Regulatory Policy

- Sale and distribution of tobacco products to persons under age 18 should be prohibited.
- Specific and increasingly stringent targets for the reduction of tobacco use by children and adolescents (also known as "performance standards") should be established and become binding on the tobacco industry by brand within the next two years. [In its deliberations, the Advisory Committee recommended that a ten-year plan be established that is at least as strong as the following: At the end of Reduction target Year 2 15% Year 3 20% Year 4 25% Year 5 30% Year 6 40% Year 7 50% Year 8 55% Year 9 60% Year 10 65%]. Failure by the tobacco industry to meet these targets should result in predictable financial penalties sufficiently severe to act as a strong deterrent to continued failure.

Included within this recommendation are such specific proposals as:

- Penalties should be structured so that failure to meet the targets directly reduces total revenue and affects total shareholder value.
- Such penalties should not be arbitrarily limited or capped.
- Additional non-financial penalties should be imposed if tobacco companies fail to meet such targets.
- Penalties should be assessed, to the maximum extent feasible, on a company-by-company basis.

- Similar goals and penalties should be established for smokeless tobacco and other tobacco products.
- Marketing, promotion, and advertising of all tobacco products directed at persons under age 18 should be banned.
- Included within this recommendation are such specific proposals as:
 - Services, goods, and other items that carry tobacco brand names, logos, or imagery should be banned.
 - Sponsorship of any athletic, social, or cultural events using the name of tobacco products present or future should be banned.
 - Promotion in public entertainment, including product placement in movies and television should be banned.
 - Sales and distribution of tobacco products through means that might make them available to underage users should be prohibited.
- Included within this recommendation are such specific proposals as:
 - Sales of tobacco products through vending machines, mail order, Internet and other electronic systems, and self-serve displays should be banned.
 - Sales of tobacco products near schools, playgrounds, and other areas where children congregate should be banned.
 - Sales of tobacco products near health care facilities should be banned.
 - The distribution of tobacco products through free samples or through individual or small sales should be banned.
 - States should license all participants in tobacco sales (e.g., manufacturers, distributors, wholesalers, importers, etc.), and penalties for violations of sales to minors should be strict enough to ensure compliance with the law.
 - Both State and Local governments should be allowed to enforce violations of such restrictions and licensing requirements.
 - The warning and product content labeling on all tobacco products should be strengthened.
 - Schools and other child-service institutions should adopt and enforce a "zero-tolerance" policy against tobacco use that applies to both minors and employees.
- Included within this recommendation are such specific proposals as:

- A zero-tolerance policy should apply not only at school or on-site, but also to all sponsored events and other sanctioned activities.
- A zero-tolerance policy should include the banning of the wearing and carrying of clothing and other items that include promotional material for tobacco products.

Public Education and Other Public Health Policy

- Broad programs of counter-advertising should be required in all media markets and should be funded or supported by the tobacco industry.
- Schools should implement the Centers for Disease Control and Prevention guidelines to prevent tobacco use and addiction.
- Schools should institute comprehensive tobacco prevention programs from pre-kindergarten through 12th grade, and such programs should be funded or supported by the tobacco industry.
- IMPACT and ASSIST grants [IMPACT grants are administered by the Centers for Disease Control and Prevention. ASSIST grants are administered by the National Institutes for Health.] programs should be continued and strengthened.
- Partnerships between public entities (such as schools) and businesses should be instituted to help achieve continued reduction in underage use of tobacco products.
- Health care providers should be educated about effective means to prevent children from beginning tobacco use.
- Tobacco use by children and adolescents should be included as an outcome measure in assessing the quality of health care services (e.g., in HEDIS and other NCQA reviews).

Research Policy

- Research should be conducted on the reduction of underage tobacco use.
- Included within this recommendation are such specific proposals as research on:
- Methods of identifying children who are likely to begin (or increase) use of tobacco products.
- The effectiveness of current prevention and education efforts on youth consumption.
- Children's and parents' attitudes and beliefs about tobacco use and the perception of risk, understanding of addiction, and the long-term consequences of tobacco use by children.

Fiscal Policy

Fiscal Policy

- Excise taxes on tobacco products should be dramatically increased and should be indexed to inflation. [Economic analyses suggest that children's use of tobacco is significantly affected by price increases of \$2 per pack or more]
- Fines from performance standards violations should not be tax-deductible.
- Fines from performance standards violations should be used to support activities to reduce tobacco consumption, with emphasis on activities designed to reduce consumption by children and adolescents.
- The enforcement of regulations and the initiation of public education, public health, and research efforts should be funded by these excise taxes, fines from performance standards violations, and by other funds from the tobacco industry.
- A new non-profit corporation to support tobacco prevention and control programs should be established in the private sector and should be funded by the tobacco industry, by excise taxes, and by fines from performance standard violations. The start-up of the non-profit corporation and its educational activities should begin at the earliest possible time.

Summary of Major Recommendations of the Task Force on Current Users of Tobacco Products

BACKGROUND

Some 50 million Americans are now addicted to tobacco. One of every three long-term users of tobacco will die from a disease related to their tobacco use. [Coalition on Smoking OR Health, Protecting Our Families and Children from Tobacco: Public Policy Activities of the Coalition on Smoking or Health for 1995 and 1996 , 2 (1996).] Nicotine, a major constituent of tobacco, is highly addictive and "cigarettes and other forms of tobacco are just as addicting as heroin and cocaine. . . ." [Addiction Research Foundation, Facts about Tobacco , 2 (undated) (citing the United State's Surgeon General's 1988 Report on Smoking).] Similarly, withdrawal from this addiction is like withdrawal from other highly addictive substances. About 70 percent of smokers want to quit, but less than one-quarter are successful in doing so.

The Agency for Health Care Research and Policy has issued smoking cessation clinical practice guidelines [Agency for Health Care Policy and Research, Smoking Cessation (Clinical Practice Guideline, Number 18) (1996) (reprinted in 275 J.A.M.A. 16 (April 24, 1996)).] that lay out recommendations for primary care clinicians, smoking cessation specialists, and health care administrators, insurers, and purchasers. These guidelines are often cited as the framework for providing and evaluating smoking cessation services.

In a separate but related area, it should be noted that cigarette-caused fires are the leading cause of deaths from residential fires. It is argued that many such fires could be prevented by changes that would reduce the burn characteristics of cigarettes.

RECOMMENDATIONS

RECOMMENDATIONS

Regulatory Policy

- Coverage for tobacco use cessation programs and services should be required under all health insurance, managed care, and employee benefit plans, as well as all Federal health financing programs (e.g., Medicare and Medicaid). Such coverage should be provided as a lifetime benefit rather than as a one-time opportunity to "kick the habit."
- Tobacco use cessation programs and services should be available to adults, adolescents, and children who are addicted to tobacco products, regardless of their insurance status or ability to pay.

Public Education and Other Public Health Policy

- The smoking cessation guidelines issued by the Agency for Health Care Policy and Research [Agency for Health Care Policy and Research, Smoking Cessation (Clinical Practice Guideline, Number 18) (1996) (reprinted in 275 J.A.M.A. 16 (April 24, 1996)).] should serve as the cornerstone for health care providers engaged in clinical practice.
- Courses on the prevention, treatment, and control of tobacco use, including cessation, should be made a part of the core curriculum in the education of health professionals.
- Tobacco use cessation programs and services should be made widely available. Specific cessation programs and services should be developed for specific populations, including children, women, racial and ethnic minorities, and individuals with limited literacy.
- Substantial public education efforts designed to inform tobacco users about both the health hazards of tobacco and the availability of tobacco use cessation programs and services should be undertaken.
- Policies designed to reduce the number of fires caused by tobacco products should be developed and implemented.

Research Policy

- Research efforts designed to evaluate the effectiveness of tobacco use cessation programs, services and therapeutics should be undertaken.
- Research projects should include work on smokeless tobacco and cigar use as well as cigarette smoking.
- Research projects should focus on the development of tobacco use cessation programs and services for pregnant women, children, and adolescents.
- Research efforts designed to evaluate the effectiveness of public education and

- Research efforts designed to evaluate the effectiveness of public education and public health policies in successfully encouraging current users of tobacco products to attempt cessation efforts should be undertaken.

Fiscal Policy

- Tobacco use cessation programs and services should be funded or supported by the tobacco industry at a level sufficient to ensure that they are provided universally and in a manner most likely to prove effective.
- Research efforts related to the development of effective tobacco use cessation programs and services should be funded or supported by the tobacco industry.

Summary of Major Recommendations of the Task Force on Environmental Tobacco Smoke

BACKGROUND

Second-hand or environmental tobacco smoke (ETS) is no longer considered just an unpleasant side effect of cigarette smoking. Scientific evidence now indicates that nonsmokers become seriously ill or die because of exposure to the toxic smoke produced by other people's active smoking and the U.S. Environmental Protection Agency has classified ETS as an agent known to cause cancer in humans. [U.S. Environmental Protection Agency, Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders, (Dec. 1992) (EPA/600/6-90/006F).] ETS is believed to cause tens of thousands of deaths each year and to cause or exacerbate cardiovascular and pulmonary illnesses in hundreds of thousands additional individuals.

ETS is of particular concern with regard to children. Children are powerless to control their exposure to ETS and yet, because of their young age, are most adversely affected by exposure to this agent. The EPA estimates that exposure to ETS from parental smoking alone causes as many as 300,000 lower respiratory infections per year in infants under the age of 18 months. [Id .]

Efforts to control second-hand smoke have been undertaken at Federal, State, and Local levels of government. The Federal government has banned smoking in federally-assisted programs for children and on domestic airline flights. Forty-eight States and the District of Columbia have enacted laws that, in some way, restrict smoking in public places. Local governments have usually led the way in these efforts; over 800 local communities have adopted significant restrictions on smoking in public places and workplaces.

RECOMMENDATIONS

Regulatory Policy

- Legislation or regulations should be enacted and enforced by Local, State, and Federal governments to eliminate exposure to second-hand smoke.
- Included within this recommendation are such specific proposals as:

- Smoking should be banned in all work sites and in all places of public assembly, especially those in places in which children are present.
- Smoking should be banned in outdoor areas where people assemble, such as service lines, seating areas of sports stadiums and arenas, etc.
- Schools should be required to be 100 percent smoke-free in all areas of their campuses.
- Smoking should be banned on all forms of public transportation, including bus, train, commuter services, and flights originating in or arriving at the U.S.
- Smoking should be banned at all Federal workplaces, including branches of the military and the Department of Veterans' Affairs and its hospitals.

Public Education and Other Public Health Policy

- A comprehensive public education and public awareness program about the dangers of ETS should be funded and implemented by Local, State, and Federal levels of government.
- State and local school boards should revise school health education programs to include information on ETS and its health effects.

Research Policy

- Federal health agencies should complete a risk assessment of the cardiovascular effects of ETS.

Fiscal Policy

- Economic incentives for smoke-free workplaces should be developed.
- Included within this recommendation are such specific proposals as:
 - Insurers should be encouraged to take into account worksite smoke-free policies in assessing appropriate premiums for health insurance, business insurance, and workers' compensation coverage.

Summary of Major Recommendations of the Task Force on the Future of the Tobacco Industry and Tobacco Control Efforts

BACKGROUND

This task force reviewed three basic areas and made recommendations regarding each one. The three areas were: (1) common threads of domestic tobacco control efforts that cut across all other task force recommendations; (2) activities to aid those Americans who will be disadvantaged through no fault of their own by tobacco control policies; and (3) U.S. activities that can assist in tobacco control internationally.

(3) U.S. activities that can assist in tobacco control internationally.

In the first area, it is clear that many of the problems identified by the other four task forces have common sources and potentially common solutions. Most of these task forces made recommendations, for example, opposing preemption of State and local standards. Rather than repeating these proposals in each task force summary, these suggested actions are consolidated here: They should be read to be a part of each task force, unless specific circumstances dictate a narrower approach as reflected in the respective task force summary.

In the second area, this task force reports that tobacco farmers and farm communities are at severe economic risk as comprehensive tobacco control policies take effect. Most Americans consider the tobacco farmer to be as much an economic victim as a participant in the manufacture of tobacco products and support government efforts to help tobacco farmers find other means of making a living.

In the third area, this task force focused on the need for international tobacco policy to which the U.S. could make a substantial contribution. According to the World Health Organization, in the early 1990's, tobacco use caused three million deaths a year worldwide; WHO goes on to project that within the next twenty to thirty years, this number will rise to ten million deaths a year, with 70 percent of those deaths occurring in developing countries. Many of these deaths and projected deaths can be attributed to the increasingly aggressive marketing efforts of U.S.- based transnational tobacco companies.

RECOMMENDATIONS

Tobacco Control Efforts

Regulatory Policy

- Any Federal or State regulation of tobacco products should contain unambiguous non-preemption provisions, expressly clarifying that higher standards of public health protection imposed by State and Local governments are preserved.
- Federal, State, and Local tobacco control regulations should be aggressively enforced and such enforcement activities should be fully funded and supported.
- All currently available avenues of litigation, both civil and criminal, must be fully preserved.
- All elements of Federal, State, and Local tobacco control policies should be enforceable through lawsuits sought by individual citizens.
- All internal tobacco company documents that bear upon the public health must be disclosed.
- Included within this recommendation are such specific proposals as:
- Disclosure of the companies' and their affiliates' public relations, advertising,

- Disclosure of the companies' and their affiliates' public relations, advertising, promotion, marketing, and political activities.
- Disclosure of all information inappropriately shielded by an assertion of attorney-client privilege.
- Disclosure of all technical and health/safety data (with a possible exception for those true trade secrets that the companies can clearly establish have no health implications).
- Disclosure of all information related to marketing, including opinion and behavioral research; and the targeting of children, women, and racial and ethnic minorities.
- Disclosure of all documents relating to the effects of second-hand smoke.
- A Federal oversight board should be established to investigate all matters relating to public health and tobacco products and the tobacco industry.
- Included within this recommendation are such specific proposals as:
 - The board should have investigative authorities, including subpoena power, necessary to investigate all matters regarding tobacco policy and public health.

Research Policy

- The collection and analysis of comprehensive data on tobacco use, behavior, attitudes (at national, regional, state, and local levels) should be funded or supported.
- Federal agencies and their partners should support programs to research, develop, and disseminate information regarding innovative interventions, including demonstration projects for implementing effective interventions.

Fiscal Policy

- Significant excise taxes (indexed to inflation) should be imposed upon tobacco products, both as a means of reducing consumption [Economic analyses suggest that children's use of tobacco is significantly affected by price increases of \$2 per pack or more.] and as a means of raising revenues as one source of support for tobacco control activities.
- All tobacco control activities (including education, counter-advertising, smoking cessation, etc.) funded or supported in whole or in part by the tobacco industry should be developed and implemented in a manner entirely independent of the industry.
- Fines, punitive damages, and other forms of financial punishment imposed on the tobacco industry and its affiliates should not be recognized as an ordinary business

expense and should not be tax-deductible or given other special tax treatment.

- Fines collected for failure to meet performance standards or violations of sales and promotion restrictions should be used for tobacco control activities.
- Funding for Federal, State, and Local tobacco control activities (including regulation and enforcement activities) should be sufficient to allow the effective conduct of such efforts.
- Funding for nongovernmental tobacco control activities should be sufficient to allow the effective conduct of such efforts. Particular emphasis should be placed on community programs for racial and ethnic minorities.
- Future smoking cessation programs and services should be entirely financed by the tobacco industry, regardless of location of service delivery or initial source of payment. Individuals and third-party payors (both public and private) should receive full reimbursement (or subrogation, as appropriate) for the costs of all future smoking cessation programs or services, without restriction on extrapolation, aggregation, or other means of consolidation.

Tobacco Farms and Farm Communities

Public Education and Other Public Health Policy

- A blue-ribbon panel should be established to oversee tobacco growing, manufacturing, and marketing policy, including the history of domestic and foreign tobacco purchases. This panel should provide both short- and long-term strategies for reducing the dependence of tobacco-growing States and communities on tobacco, including recommendations for the provision of economic development assistance.

Fiscal Policy

- An economic assistance and development fund should be established (and funded by the tobacco industry) to assist tobacco farmers and their communities in developing alternatives to tobacco farming. Economic conversion funds should also be provided to assist tobacco manufacturing workers and related non-farm workers.
- Federal price support programs for tobacco should be eliminated.

International Tobacco Policy Regulatory Policy

- The U.S. should actively promote tobacco control worldwide.
- Included within this recommendation are such specific proposals as:
 - The U.S. should actively promote the global adoption of U.S. domestic tobacco control policies through all appropriate international activities.

- The U.S. should support the development and implementation of tobacco control activities by multilateral organizations, including the Pan-American Health Organization, the World Health Organization, UNICEF, and the Framework Tobacco Control Convention.
- The U.S. should support the development and implementation of tobacco control activities by non- governmental organizations.
- The U.S. should support bilateral and multilateral treaties making the Framework Convention legally binding on all countries.
- The U.S. should remove tobacco products from Section 301 of the 1974 Trade Act and should prohibit U.S. government interference in international activities or the national tobacco control activities of other countries.
- The U.S. should support the development of a non-governmental International Tobacco Control Commission, governed by public health leaders. Such a commission would (1) monitor international control efforts; (2) develop uniform standards, review procedures, and provide support for non-governmental organizations advocating tobacco control; and (3) administer an international information exchange of all available tobacco industry documents.

Research Policy

- The U.S. should support international research efforts to determine the most effective means of preventing the initiation of tobacco use and of smoking cessation.

Fiscal Policy

- The U.S. should provide financial support for international governmental and non-governmental efforts to control tobacco use.

Appendices omitted but will be included soon.



**Core Principles
for
Consideration of the Resolution of
Current Outstanding Tobacco Issues**

Any resolution of the current outstanding tobacco issues - whether in the Courts, in Congress, or elsewhere - should be guided by a number of clearly enunciated principles. They include:

- 1) Regulatory Authority: The FDA Must Have The Authority To Regulate the Manufacture, Sale, Labeling, Distribution, and Marketing of Tobacco Products.**
- 2) Minimum Standard: The Current FDA Requirements Governing Youth Access and Tobacco Marketing Are Essential Minimum Components of any Public Policy Initiative. The Agency's Ability to Augment These Requirements Should Not be Curtailed.**
- 3) The Rights of Victims of the Tobacco Industry to Seek Compensation for the Injuries They Have Suffered Should Not be Abridged and The Tobacco Industry Should Not Be Immunized From Accountability for Its Wrongdoing.**
- 4) Public Education: A Well Funded, Effective Sustained Public Education Campaign That is Protected From Political Pressure is Critical to Reducing Tobacco Use.**
- 5) Preemption: Congress Should Not Preempt State or Local Laws That Are Stronger Than Federal laws, Nor Should the FDA Be Preempted from Revising the Form, Content, and Placement of the Warnings on Cigarette Packs.**
- 6) Public Disclosure: The Tobacco Industry Must Disclose its Research and Studies About the effects of its Products, including Nicotine, on the Human Body and the Marketing of Tobacco To Children.**

In addition to these six principles, it is vital to recognize that there are other issues which are key components of any overall comprehensive tobacco control plan, including items such as increased tobacco taxes, protection of nonsmokers from environmental tobacco smoke, and the role of the American tobacco industry in international tobacco sales.



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06/26/97 12:48:07 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Paul J. Weinstein Jr./OPD/EOP, Elizabeth Drye/OPD/EOP

cc: Christopher C. Jennings/OPD/EOP, Toby Donenfeld/OVP @ OVP

Subject: FYI... Koop-Kessler recommendation on performance penalties

I wrote this down from their meeting yesterday. These are the points that were agreed to by consensus (including Heart, Cancer, AMA, the Campaign) for inclusion in their "blueprint," which is their effort to set the right public health agenda. They will also have a second document, a "letter," that will be a side-by-side of their blueprint and the proposed settlement.

"First, and most important: Failure to meet youth smoking reduction targets must lead to severe, predictable sanctions that would serve as a significant financial deterrent directly affecting shareholder value of industry companies.

2. The tobacco industry should be required to meet increasingly stringent youth tobacco consumption reduction targets every year, beginning with the second year.

3. No caps on any penalties that are related to meeting targets.

4. Will remain silent in blueprint on this matter because it is not a public health question, but decided there should not be a rebate or abatement provisions.

5. There should be non-financial penalties (e.g., plain packaging) for missing youth reduction targets.

6. Funds collected from penalties should be used to further reduce consumption of tobacco products with youth as the first priority.

7. Performance penalties should be assessed on a company by company basis.

8. There should be some industry oversight apparatus to help insure compliance with the youth reduction targets that would include review of industry behavior and help insure appropriate incentives."

**FINAL REPORT
OF
THE ADVISORY COMMITTEE ON
TOBACCO POLICY AND PUBLIC HEALTH**

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INTRODUCTION BY THE CO-CHAIRS

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SUMMARY OF MAJOR RECOMMENDATIONS OF THE TASK FORCE ON THE REGULATION OF NICOTINE AND TOBACCO PRODUCTS

BACKGROUND

"[N]icotine in cigarettes and smokeless tobacco has the same pharmacological effects as other drugs that FDA has traditionally regulated."¹ Indeed, it is acknowledged that nicotine is extremely addictive and that "the vast majority of people who use nicotine-containing cigarettes and smokeless tobacco do so to satisfy their craving for the pharmacological effects of nicotine; that is, to satisfy their drug-dependence or addiction."² Many would argue, therefore, that the regulation of nicotine and its delivery is itself the most essential element of tobacco control activities.

Other components of tobacco smoke are also toxic. The tar, carbon monoxide, and additives contained therein are dangerous to the health of those using tobacco and those around them.

RECOMMENDATIONS

Regulatory Policy

- FDA should continue to have authority to regulate all areas of nicotine, as well as other constituents and ingredients, and that authority should be made completely explicit.
- FDA should continue to have the authority to phase out nicotine and remove ingredients that contribute to the initiation of smoking and dependence on cigarettes and other tobacco products (including smokeless tobacco, pipes, cigars, and roll-your-own tobacco), and that authority should be made completely explicit.
- There should be no limitations on or special exceptions to FDA authority to regulate nicotine, other constituents, and ingredients of tobacco products and such a no-limitations policy should be made completely explicit.

¹ 61 Fed. Reg. 168, 44661 (1996).

² *Id.* at 44636 (comments of the American Heart Association, the American Lung Association, and the American Cancer Society).

- The FDA should continue to have authority to regulate further nicotine, other constituents, and ingredients as the evidence suggests. The best science, information, and health policy (and not an arbitrary deadline) should drive FDA regulatory timing and that authority should be made completely explicit.
- The FDA should have the authority to test nicotine levels by brand, based on the best science and that authority should be made completely explicit.
- Regulation of non-tobacco nicotine delivery devices (e.g., nicotine patches, nicotine gum, nicotine inhalers, etc.) should be done in a manner that does not make the development and sale of less hazardous systems difficult and that encourages maximum overall reduction in disease.

Research Policy

- FDA should have the authority and funding to conduct research on nicotine and other components of tobacco products.
- International exchange and scientific conferences on nicotine and other components of tobacco products should be convened among private industry researchers and public researchers (such as those from the FDA, the CDC, the NIH, and the WHO).
- Research should be conducted on the effects of nicotine in children and adolescents.

Fiscal Policy

- FDA should be adequately funded to carry out its regulatory, enforcement, public education, and research activities.

SUMMARY OF MAJOR RECOMMENDATIONS OF THE TASK FORCE ON YOUTH AND TOBACCO

BACKGROUND

More than 90 percent of people who will ever smoke on a regular basis begin doing so prior to the age of 19. Each day, some 3,000 children take up the habit; the average age at which they begin is approximately 12-1/2, although many decide to smoke earlier if they are able. While these children start to use tobacco for a variety of reasons, very quickly they become addicted to the nicotine present in the product, and studies show clearly that children have just as difficult a time quitting as do adults.

There are a number of reasons why children begin to use tobacco. Among these are the remarkably effective advertising and promotion by the tobacco industry and, for many young people, perceived benefits from the use of tobacco, be they adult privileges, appealing images, or the opportunity for rebelliousness.

RECOMMENDATIONS

Regulatory Policy

- Sale and distribution of tobacco products to persons under age 18 should be prohibited.
- Specific and increasingly stringent targets for the reduction of tobacco use by children and adolescents (also known as "performance standards") should be established and become binding on the tobacco industry by brand within the next two years.³ Failure by the tobacco industry to meet

³ In its deliberations, the Advisory Committee recommended that a ten-year plan be established that is *at least* as strong as the following:

<u>At the end of</u>	<u>Reduction target</u>
Year 2	15%
Year 3	20%
Year 4	25%
Year 5	30%
Year 6	40%
Year 7	50%
Year 8	55%
Year 9	60%
Year 10	65%.

these targets should result in predictable financial penalties sufficiently severe to act as a strong deterrent to continued failure.

- Included within this recommendation are such specific proposals as:
 - Penalties should be structured so that failure to meet the targets directly reduces total revenue and affects total shareholder value.
 - Such penalties should not be arbitrarily limited or capped.
 - Additional non-financial penalties should be imposed if tobacco companies fail to meet such targets.
 - Penalties should be assessed, to the maximum extent feasible, on a company-by-company basis.
 - Similar goals and penalties should be established for smokeless tobacco and other tobacco products.
- Marketing, promotion, and advertising of all tobacco products directed at persons under age 18 should be banned.
 - Included within this recommendation are such specific proposals as:
 - Services, goods, and other items that carry tobacco brand names, logos, or imagery should be banned.
 - Sponsorship of any athletic, social, or cultural events using the name of tobacco products present or future should be banned.
 - Promotion in public entertainment, including product placement in movies and television should be banned.
- Sales and distribution of tobacco products through means that might make them available to underage users should be prohibited.
 - Included within this recommendation are such specific proposals as:
 - Sales of tobacco products through vending machines, mail order, Internet and other electronic systems, and self-serve displays should be banned.
 - Sales of tobacco products near schools, playgrounds, and other areas where children congregate should be banned.
 - Sales of tobacco products near health care facilities should be banned.
 - The distribution of tobacco products through free samples or through individual or small sales should be banned.

- States should license all participants in tobacco sales (e.g., manufacturers, distributors, wholesalers, importers, etc.), and penalties for violations of sales to minors should be strict enough to ensure compliance with the law.
- Both State and Local governments should be allowed to enforce violations of such restrictions and licensing requirements.
- The warning and product content labeling on all tobacco products should be strengthened.
- Schools and other child-service institutions should adopt and enforce a “zero-tolerance” policy against tobacco use that applies to both minors and employees.
- Included within this recommendation are such specific proposals as:
 - A zero-tolerance policy should apply not only at school or on-site, but also to all sponsored events and other sanctioned activities.
 - A zero-tolerance policy should include the banning of the wearing and carrying of clothing and other items that include promotional material for tobacco products.

Public Education and Other Public Health Policy

- Broad programs of counter-advertising should be required in all media markets and should be funded or supported by the tobacco industry.
- Schools should implement the Centers for Disease Control and Prevention guidelines to prevent tobacco use and addiction.
- Schools should institute comprehensive tobacco prevention programs from pre-kindergarten through 12th grade, and such programs should be funded or supported by the tobacco industry.
- IMPACT and ASSIST grants⁴ programs should be continued and strengthened.

⁴ IMPACT grants are administered by the Centers for Disease Control and Prevention. ASSIST grants are administered by the National Institutes of Health.

- Partnerships between public entities (such as schools) and businesses should be instituted to help achieve continued reduction in underage use of tobacco products.
- Health care providers should be educated about effective means to prevent children from beginning tobacco use.
- Tobacco use by children and adolescents should be included as an outcome measure in assessing the quality of health care services (e.g., in HEDIS and other NCQA reviews).

Research Policy

- Research should be conducted on the reduction of underage tobacco use.
- Included within this recommendation are such specific proposals as research on:
 - Methods of identifying children who are likely to begin (or increase) use of tobacco products.
 - The effectiveness of current prevention and education efforts on youth consumption.
 - Children's and parents' attitudes and beliefs about tobacco use and the perception of risk, understanding of addiction, and the long-term consequences of tobacco use by children.

Fiscal Policy

- Excise taxes on tobacco products should be dramatically increased and should be indexed to inflation.⁵
- Fines from performance standards violations should not be tax-deductible.
- Fines from performance standards violations should be used to support activities to reduce tobacco consumption, with emphasis on activities designed to reduce consumption by children and adolescents.

⁵ Economic analyses suggest that children's use of tobacco is significantly affected by price increases of \$2 per pack or more.

- The enforcement of regulations and the initiation of public education, public health, and research efforts should be funded by these excise taxes, fines from performance standards violations, and by other funds from the tobacco industry.
- A new non-profit corporation to support tobacco prevention and control programs should be established in the private sector and should be funded by the tobacco industry, by excise taxes, and by fines from performance standard violations. The start-up of the non-profit corporation and its educational activities should begin at the earliest possible time.

SUMMARY OF MAJOR RECOMMENDATIONS OF THE TASK FORCE ON CURRENT USERS OF TOBACCO PRODUCTS

BACKGROUND

Some 50 million Americans are now addicted to tobacco. One of every three long-term users of tobacco will die from a disease related to their tobacco use⁶ Nicotine, a major constituent of tobacco, is highly addictive and "cigarettes and other forms of tobacco are just as addicting as heroin and cocaine. . . ."⁷ Similarly, withdrawal from this addiction is like withdrawal from other highly addictive substances. About 70 percent of smokers want to quit, but less than one-quarter are successful in doing so.

The Agency for Health Care Research and Policy has issued smoking cessation clinical practice guidelines⁸ that lay out recommendations for primary care clinicians, smoking cessation specialists, and health care administrators, insurers, and purchasers. These guidelines are often cited as the framework for providing and evaluating smoking cessation services.

In a separate but related area, it should be noted that cigarette-caused fires are the leading cause of deaths from residential fires. It is argued that many such fires could be prevented by changes that would reduce the burn characteristics of cigarettes.

RECOMMENDATIONS

Regulatory Policy

- Coverage for tobacco use cessation programs and services should be required under all health insurance, managed care, and employee benefit plans, as well as all Federal health financing programs (e.g., Medicare and Medicaid). Such coverage should be provided as a lifetime benefit rather than as a one-time opportunity to "kick the habit."

⁶ Coalition on Smoking OR Health, Protecting Our Families and Children from Tobacco: Public Policy Activities of the Coalition on Smoking or Health for 1995 and 1996, 2 (1996).

⁷ Addiction Research Foundation, Facts About Tobacco, 2 (undated)(citing the United States Surgeon General's 1988 Report on Smoking).

⁸ Agency for Health Care Policy and Research, Smoking Cessation (Clinical Practice Guideline, Number 18) (1996) (reprinted in 275 J.A.M.A. 16 (April, 24, 1996)).

- Tobacco use cessation programs and services should be available to adults, adolescents, and children who are addicted to tobacco products, regardless of their insurance status or ability to pay.

Public Education and Other Public Health Policy

- The smoking cessation guidelines issued by the Agency for Health Care Policy and Research⁹ should serve as the cornerstone for health care providers engaged in clinical practice.
- Courses on the prevention, treatment, and control of tobacco use, including cessation, should be made a part of the core curriculum in the education of health professionals.
- Tobacco use cessation programs and services should be made widely available. Specific cessation programs and services should be developed for specific populations, including children, women, racial and ethnic minorities, and individuals with limited literacy.
- Substantial public education efforts designed to inform tobacco users about both the health hazards of tobacco and the availability of tobacco use cessation programs and services should be undertaken.
- Policies designed to reduce the number of fires caused by tobacco products should be developed and implemented.

Research Policy

- Research efforts designed to evaluate the effectiveness of tobacco use cessation programs, services and therapeutics should be undertaken.
- Research projects should include work on smokeless tobacco and cigar use as well as cigarette smoking.
- Research projects should focus on the development of tobacco use cessation programs and services for pregnant women, children, and adolescents.

⁹ Agency for Health Care Policy and Research, Smoking Cessation (Clinical Practice Guideline, Number 18) (1996) (reprinted in 275 J.A.M.A. 16 (April, 24, 1996)).

- Research efforts designed to evaluate the effectiveness of public education and public health policies in successfully encouraging current users of tobacco products to attempt cessation efforts should be undertaken.

Fiscal Policy

- Tobacco use cessation programs and services should be funded or supported by the tobacco industry at a level sufficient to ensure that they are provided universally and in a manner most likely to prove effective.
- Research efforts related to the development of effective tobacco use cessation programs and services should be funded or supported by the tobacco industry.

SUMMARY OF MAJOR RECOMMENDATIONS OF THE TASK FORCE ON ENVIRONMENTAL TOBACCO SMOKE

BACKGROUND

Second-hand or environmental tobacco smoke (ETS) is no longer considered just an unpleasant side effect of cigarette smoking. Scientific evidence now indicates that nonsmokers become seriously ill or die because of exposure to the toxic smoke produced by other people's active smoking and the U.S. Environmental Protection Agency has classified ETS as an agent known to cause cancer in humans.¹⁰ ETS is believed to cause tens of thousands of deaths each year and to cause or exacerbate cardiovascular and pulmonary illnesses in hundreds of thousands additional individuals.

ETS is of particular concern with regard to children. Children are powerless to control their exposure to ETS and yet, because of their young age, are most adversely affected by exposure to this agent. The EPA estimates that exposure to ETS from parental smoking alone causes as many as 300,000 lower respiratory infections per year in infants under the age of 18 months.¹¹

Efforts to control second-hand smoke have been undertaken at Federal, State, and Local levels of government. The Federal government has banned smoking in federally-assisted programs for children and on domestic airline flights. Forty-eight States and the District of Columbia have enacted laws that, in some way, restrict smoking in public places. Local governments have usually led the way in these efforts; over 800 local communities have adopted significant restrictions on smoking in public places and workplaces.

RECOMMENDATIONS

Regulatory Policy

- Legislation or regulations should be enacted and enforced by Local, State, and Federal governments to eliminate exposure to second-hand smoke.
- Included within this recommendation are such specific proposals as:

¹⁰ U.S. Environmental Protection Agency, Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders, (Dec. 1992)(EPA /600/6-90/006F).

¹¹ *Id.*

- Smoking should be banned in all work sites and in all places of public assembly, especially those in places in which children are present.
 - Smoking should be banned in outdoor areas where people assemble, such as service lines, seating areas of sports stadiums and arenas, etc.
 - Schools should be required to be 100 percent smoke-free in all areas of their campuses.
- Smoking should be banned on all forms of public transportation, including bus, train, commuter services, and flights originating in or arriving at the U.S.
 - Smoking should be banned at all Federal workplaces, including branches of the military and the Department of Veterans' Affairs and its hospitals.

Public Education and Other Public Health Policy

- A comprehensive public education and public awareness program about the dangers of ETS should be funded and implemented by Local, State, and Federal levels of government.
- State and local school boards should revise school health education programs to include information on ETS and its health effects.

Research Policy

- Federal health agencies should complete a risk assessment of the cardiovascular effects of ETS.

Fiscal Policy

- Economic incentives for smoke-free workplaces should be developed.
- Included within this recommendation are such specific proposals as:
 - Insurers should be encouraged to take into account worksite smoke-free policies in assessing appropriate premiums for health insurance, business insurance, and workers' compensation coverage.

SUMMARY OF MAJOR RECOMMENDATIONS OF THE TASK FORCE ON THE FUTURE OF THE TOBACCO INDUSTRY AND TOBACCO CONTROL EFFORTS

BACKGROUND

This task force reviewed three basic areas and made recommendations regarding each one. The three areas were: (1) common threads of domestic tobacco control efforts that cut across all other task force recommendations; (2) activities to aid those Americans who will be disadvantaged through no fault of their own by tobacco control policies; and (3) U.S. activities that can assist in tobacco control internationally.

In the first area, it is clear that many of the problems identified by the other four task forces have common sources and potentially common solutions. Most of these task forces made recommendations, for example, opposing preemption of State and local standards. Rather than repeating these proposals in each task force summary, these suggested actions are consolidated here: They should be read to be a part of each task force, unless specific circumstances dictate a narrower approach as reflected in the respective task force summary.

In the second area, this task force reports that tobacco farmers and farm communities are at severe economic risk as comprehensive tobacco control policies take effect. Most Americans consider the tobacco farmer to be as much an economic victim as a participant in the manufacture of tobacco products and support government efforts to help tobacco farmers find other means of making a living.

In the third area, this task force focused on the need for international tobacco policy to which the U.S. could make a substantial contribution. According to the World Health Organization, in the early 1990's, tobacco use caused three million deaths a year worldwide; WHO goes on to project that within the next twenty to thirty years, this number will rise to ten million deaths a year, with 70 percent of those deaths occurring in developing countries. Many of these deaths and projected deaths can be attributed to the increasingly aggressive marketing efforts of U.S.-based transnational tobacco companies.

RECOMMENDATIONS

Tobacco Control Efforts

Regulatory Policy

- Any Federal or State regulation of tobacco products should contain unambiguous non-preemption provisions, expressly clarifying that higher standards of public health protection imposed by State and Local governments are preserved.
- Federal, State, and Local tobacco control regulations should be aggressively enforced and such enforcement activities should be fully funded and supported.
- All currently available avenues of litigation, both civil and criminal, must be fully preserved.
- All elements of Federal, State, and Local tobacco control policies should be enforceable through lawsuits sought by individual citizens.
- All internal tobacco company documents that bear upon the public health must be disclosed.
- Included within this recommendation are such specific proposals as:
 - Disclosure of the companies' and their affiliates' public relations, advertising, promotion, marketing, and political activities.
 - Disclosure of all information inappropriately shielded by an assertion of attorney-client privilege.
 - Disclosure of all technical and health/safety data (with a possible exception for those true trade secrets that the companies can clearly establish have no health implications).
 - Disclosure of all information related to marketing, including opinion and behavioral research; and the targeting of children, women, and racial and ethnic minorities.
 - Disclosure of all documents relating to the effects of second-hand smoke.

- A Federal oversight board should be established to investigate all matters relating to public health and tobacco products and the tobacco industry.
- Included within this recommendation are such specific proposals as:
 - The board should have investigative authorities, including subpoena power, necessary to investigate all matters regarding tobacco policy and public health.

Research Policy

- The collection and analysis of comprehensive data on tobacco use, behavior, attitudes (at national, regional, state, and local levels) should be funded or supported.
- Federal agencies and their partners should support programs to research, develop, and disseminate information regarding innovative interventions, including demonstration projects for implementing effective interventions.

Fiscal Policy

- Significant excise taxes (indexed to inflation) should be imposed upon tobacco products, both as a means of reducing consumption¹² and as a means of raising revenues as one source of support for tobacco control activities.
- All tobacco control activities (including education, counter-advertising, smoking cessation, etc.) funded or supported in whole or in part by the tobacco industry should be developed and implemented in a manner entirely independent of the industry.
- Fines, punitive damages, and other forms of financial punishment imposed on the tobacco industry and its affiliates should not be recognized as an ordinary business expense and should not be tax-deductible or given other special tax treatment.

¹² Economic analyses suggest that children's use of tobacco is significantly affected by price increases of \$2 per pack or more.

- Fines collected for failure to meet performance standards or violations of sales and promotion restrictions should be used for tobacco control activities.
- Funding for Federal, State, and Local tobacco control activities (including regulation and enforcement activities) should be sufficient to allow the effective conduct of such efforts.
- Funding for nongovernmental tobacco control activities should be sufficient to allow the effective conduct of such efforts. Particular emphasis should be placed on community programs for racial and ethnic minorities.
- Future smoking cessation programs and services should be entirely financed by the tobacco industry, regardless of location of service delivery or initial source of payment. Individuals and third-party payors (both public and private) should receive full reimbursement (or subrogation, as appropriate) for the costs of all future smoking cessation programs or services, without restriction on extrapolation, aggregation, or other means of consolidation.

Tobacco Farms and Farm Communities

Public Education and Other Public Health Policy

- A blue-ribbon panel should be established to oversee tobacco growing, manufacturing, and marketing policy, including the history of domestic and foreign tobacco purchases. This panel should provide both short- and long-term strategies for reducing the dependence of tobacco-growing States and communities on tobacco, including recommendations for the provision of economic development assistance.

Fiscal Policy

- An economic assistance and development fund should be established (and funded by the tobacco industry) to assist tobacco farmers and their communities in developing alternatives to tobacco farming. Economic conversion funds should also be provided to assist tobacco manufacturing workers and related non-farm workers.
- Federal price support programs for tobacco should be eliminated.

International Tobacco Policy

Regulatory Policy

- The U.S. should actively promote tobacco control worldwide.
- Included within this recommendation are such specific proposals as:
 - The U.S. should actively promote the global adoption of U.S. domestic tobacco control policies through all appropriate international activities.
 - The U.S. should support the development and implementation of tobacco control activities by multilateral organizations, including the Pan-American Health Organization, the World Health Organization, UNICEF, and the Framework Tobacco Control Convention.
 - The U.S. should support the development and implementation of tobacco control activities by non-governmental organizations.
 - The U.S. should support bilateral and multilateral treaties making the Framework Convention legally binding on all countries.
 - The U.S. should remove tobacco products from Section 301 of the 1974 Trade Act and should prohibit U.S. government interference in international activities or the national tobacco control activities of other countries.
 - The U.S. should support the development of a non-governmental International Tobacco Control Commission, governed by public health leaders. Such a commission would (1) monitor international control efforts; (2) develop uniform standards, review procedures, and provide support for non-governmental organizations advocating tobacco control; and (3) administer an international information exchange of all available tobacco industry documents.

Research Policy

- The U.S. should support international research efforts to determine the most effective means of preventing the initiation of tobacco use and of smoking cessation.

Fiscal Policy

- The U.S. should provide financial support for international governmental and non-governmental efforts to control tobacco use.

Congress of the United States

Washington, DC 20515

May 22, 1997

Mr. John Garrison
Managing Director, American Lung Association
1740 Broadway
New York, NY 10019

Dear Mr. Garrison:

We are writing as Members of Congress to ask that you serve on an Advisory Committee on Tobacco Policy and Public Health to be chaired by Dr. C. Everett Koop and Dr. David Kessler. The Advisory Committee will advise us on any tobacco settlement that may be proposed and will work with us to develop a comprehensive and united approach to any tobacco legislation that Congress may consider.

In the talks that are now underway, the tobacco industry is seeking a "global settlement" that would provide the industry with limitations on liability, public legitimacy, and sustained economic health. We are concerned that no one has adequately analyzed the ramifications of the tobacco companies' proposal. Before Congress considers any "global settlement" with the tobacco companies, we believe that it is essential that we obtain input from a public health perspective.

We seek your help in this effort. We must not limit our focus to only one part of the tobacco control agenda. In fact, given the unprecedented nature of the relief being discussed by the negotiators for the tobacco industry, the class-action lawyers, and the attorneys general, we believe we should not necessarily limit our focus to those provisions tobacco control advocates have proposed in the past. Instead, with your help, we want to ask fundamental questions about what — from the public health perspective — the future of the industry should be like.

We will fail our responsibilities if we limit our agenda to the issues currently on the table in the so-called "global settlement" talks. We should look at issues such as reducing tobacco exports, significantly raising tobacco taxes, ensuring actual reductions in youth smoking rates, imposing special corporate responsibilities on the industry, and other important public health policies. We ask for your help in identifying the broad range of provisions that should be encompassed in any "global settlement" with the tobacco industry.

If any agreement is reached in the tobacco settlement talks currently underway, it will undoubtedly be closely reviewed and substantially revised by Congress. Indeed, no proposal from outside groups of such a far-reaching nature has ever passed Congress without a great deal of debate and modification. A unified public health position developed by the Advisory Committee will allow us to respond to any weakening amendments effectively -- and to insist on public health amendments to strengthen the legislation.

We are at a turning point in our nation's relationship with the tobacco industry. We hope you will agree to serve on the Advisory Committee on Tobacco Policy and Public Health -- and help us to ensure that any tobacco legislation is in the public health interest of our nation.

Sincerely,

Henry A. Waxman James V. Hansen Marty Meehan
Dick Durbin Frank R. Lautenberg Don Weyer
Paul Wellstone Pat Kennedy Strom Thurmond

**THE ADVISORY COMMITTEE ON
TOBACCO POLICY AND PUBLIC HEALTH**

Co-Chairs: C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.D.

Panel Members

Action on Smoking and Health

John F. Banzhaf III, Executive Director

Advocacy Institute

Michael Pertschuk, J.D., Co-Director

American Academy of Family Physicians

Robert Graham, M.D., Executive Vice President

American Academy of Pediatrics

Richard B. Heyman, M.D., Chair, Committee on Substance Abuse

George D. Comerchi, M.D., Past President, AAP

American Cancer Society

John R. Seffrin, Ph.D., Chief Executive Officer

American College of Chest Physicians

D. Robert McCaffree, M.D., F.C.C.P., President-Elect

American College of Preventive Medicine

George K. Anderson, M.D., M.P.H., President-Elect

American Heart Association

Dudley H. Hafner, Chief Staff Executive Officer

American Lung Association

John R. Garrison, Chief Executive Officer

American Medical Association

Nancy Dickey, M.D., President-Elect

Randolph Smoak, Jr., M.D., Vice-Chair, Board of Trustees

American Medical Women's Association

Eileen McGrath, J.D., C.A.E., Executive Director

American Public Health Association

Mohammad N. Akhter, M.D., M.P.H., Executive Director

Americans for Nonsmokers' Rights

Julia Carol, Co-Director

Association of State and Territorial Health Officials

Donald E. Williamson, M.D., President-Elect

Martin Wasserman, M.D., Maryland Secretary of Health

Maine Department of Human Services, Bureau of Health

Randy H. Schwartz, M.S.P.H., Director, Division of Community and Family Health

National Center for Tobacco-Free Kids

William D. Novelli, President

Matthew L. Myers, J.D., Executive Vice President

National Medical Association

Randall C. Morgan, M.D., President

Yvonnechris Smith Veal, M.D., Past President

The Onyx Group

Rev. Jesse W. Brown, Jr., M. Div., Vice President

Partnership for Prevention

Jonathan E. Fielding, M.D., M.P.H., M.B.A., Vice-Chair

Science and Public Policy Institute

Jeff Nesbit, President

Smokeless States National Program

Thomas P. Houston, M.D., Director of Smokeless States National Program Office

Stop Teenage Addiction to Tobacco

Judy Sopenski, M.Ed., Executive Director

Tobacco Products Liability Project

Richard A. Daynard, J.D., Ph.D., President, Tobacco Control Resource Center;

Chairman, Tobacco Products Liability Project

The Advisory Committee on Tobacco Policy and Public Health
Co-Chairs: Dr. C. Everett Koop and Dr. David A. Kessler

1711 N St. NW
Washington, DC 20036
(202) 833-9500

June 10, 1997

Bill Clinton
President of the United States
The White House

Dear Mr. President,

As you may be aware, we have been asked by a bipartisan group of members of Congress to convene an advisory committee on national tobacco policy. This group, which is composed of the major public health and national tobacco control groups, was formed to develop a comprehensive and rational public health policy toward tobacco.

The Advisory Committee on Tobacco Policy and Public Health met for the first time last week. It is our intention to complete our work within the next 30 days and report back to those members of Congress.

On behalf of the advisory panel, we respectfully request that you refrain from taking a position on any proposed new tobacco control legislation that might emerge from the settlement talks until the public health community has had sufficient time and opportunity to examine and consider the implications of any such proposal.

For instance, at our meeting last week, members of our advisory panel were quite concerned about reported provisions that might ultimately limit the authority of the FDA in regulating the manufacture and marketing of tobacco products.

To assist you in your deliberations, the advisory committee has embarked on an intensive, collaborative effort to establish a comprehensive blueprint for a realistic national tobacco control policy that would be acceptable to the American public.

We believe the proposals that will be made by this panel will reflect the best advice and views of the public health community. Whether or not a settlement is reached among the lawyers, the nation needs a public health blueprint against which all policy decisions should be made. We fully expect to have this blueprint ready by early July.

We thank you for your consideration of this request and look forward to working with you on this important matter.

Sincerely yours,



C. Everett Koop, M.D.



David A. Kessler, M.D.

The Advisory Committee on Tobacco Policy and Public Health
Co-Chairs: Dr. C. Everett Koop and Dr. David A. Kessler

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C. Everett Koop, M.D.



David A. Kessler, M.D.

The Advisory Committee on Tobacco Policy and Public Health
Co-Chairs: Dr. C. Everett Koop and Dr. David A. Kessler

1711 N St. NW
Washington, DC 20036
(202) 833-9500

June 10, 1997

Bill Clinton
President of the United States
The White House

Dear Mr. President,

As you may be aware, we have been asked by a bipartisan group of members of Congress to convene an advisory committee on national tobacco policy. This group, which is composed of the major public health and national tobacco control groups, was formed to develop a comprehensive and rational public health policy toward tobacco.

The Advisory Committee on Tobacco Policy and Public Health met for the first time last week. It is our intention to complete our work within the next 30 days and report back to those members of Congress.

On behalf of the advisory panel, we respectfully request that you refrain from taking a position on any proposed new tobacco control legislation that might emerge from the settlement talks until the public health community has had sufficient time and opportunity to examine and consider the implications of any such proposal.

For instance, at our meeting last week, members of our advisory panel were quite concerned about reported provisions that might ultimately limit the authority of the FDA in regulating the manufacture and marketing of tobacco products.

To assist you in your deliberations, the advisory committee has embarked on an intensive, collaborative effort to establish a comprehensive blueprint for a realistic national tobacco control policy that would be acceptable to the American public.

We believe the proposals that will be made by this panel will reflect the best advice and views of the public health community. Whether or not a settlement is reached among the lawyers, the nation needs a public health blueprint against which all policy decisions should be made. We fully expect to have this blueprint ready by early July.

We thank you for your consideration of this request and look forward to working with you on this important matter.

Sincerely yours,



C. Everett Koop, M.D.



David A. Kessler, M.D.

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House of Representatives

Washington, DC 20515-0529

HENRY A. WAXMAN
29TH DISTRICT, CALIFORNIA

TELEFAX COVER SHEET

TO:

ELIZABETH DRYE

FROM:

PHIL

Number of pages including cover sheet:

6

INFO ON THE ADVISORY
COMMITTEE AND THE
ETS BILL

If you have any problems reading this material, please call
(202) 225-3976.

Congress of the United States
Washington, DC 20515

May 22, 1997

Mr. John Garrison
Managing Director, American Lung Association
1740 Broadway
New York, NY 10019

Dear Mr. Garrison:

We are writing as Members of Congress to ask that you serve on an Advisory Committee on Tobacco Policy and Public Health to be chaired by Dr. C. Everett Koop and Dr. David Kessler. The Advisory Committee will advise us on any tobacco settlement that may be proposed and will work with us to develop a comprehensive and united approach to any tobacco legislation that Congress may consider.

In the talks that are now underway, the tobacco industry is seeking a "global settlement" that would provide the industry with limitations on liability, public legitimacy, and sustained economic health. We are concerned that no one has adequately analyzed the ramifications of the tobacco companies' proposal. Before Congress considers any "global settlement" with the tobacco companies, we believe that it is essential that we obtain input from a public health perspective.

We seek your help in this effort. We must not limit our focus to only one part of the tobacco control agenda. In fact, given the unprecedented nature of the relief being discussed by the negotiators for the tobacco industry, the class-action lawyers, and the attorneys general, we believe we should not necessarily limit our focus to those provisions tobacco control advocates have proposed in the past. Instead, with your help, we want to ask fundamental questions about what -- from the public health perspective -- the future of the industry should be like.

We will fail our responsibilities if we limit our agenda to the issues currently on the table in the so-called "global settlement" talks. We should look at issues such as reducing tobacco exports, significantly raising tobacco taxes, ensuring actual reductions in youth smoking rates, imposing special corporate responsibilities on the industry, and other important public health policies. We ask for your help in identifying the broad range of provisions that should be encompassed in any "global settlement" with the tobacco industry.

If any agreement is reached in the tobacco settlement talks currently underway, it will undoubtedly be closely reviewed and substantially revised by Congress. Indeed, no proposal from outside groups of such a far-reaching nature has ever passed Congress without a great deal of debate and modification. A unified public health position developed by the Advisory Committee will allow us to respond to any weakening amendments effectively -- and to insist on public health amendments to strengthen the legislation.

We are at a turning point in our nation's relationship with the tobacco industry. We hope you will agree to serve on the Advisory Committee on Tobacco Policy and Public Health -- and help us to ensure that any tobacco legislation is in the public health interest of our nation.

Sincerely,

Henry A. Waxman James V. Hansen Marty Meehan
Dick Durbin Frank R. Lautenberg Don Wyder
Paul Wellstone Phil Kennedy Steven D. Dalt

ADVISORY COMMITTEE ON TOBACCO POLICY AND PUBLIC HEALTH

Co-Chairs:

Dr. C. Everett Koop

Dr. David Kessler

Groups to be invited to participate in the Advisory Committee on Tobacco Policy and Public Health shall include:

Action on Smoking and Health

American Academy of Pediatrics

American Cancer Society

American Heart Association

American Lung Association

American Medical Association

American Public Health Association

Americans for Nonsmokers Rights

National Center for Tobacco-Free Kids

Stop Teenage Addiction to Tobacco

Tobacco Products Liability Project

H.R.3434
AMENDMENT IN THE NATURE OF A SUBSTITUTE
OFFERED BY MR. WAXMAN
[New language shown underlined]

Strike out all after the enacting clause and Insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Smoke-Free Environment Act of 1993".

SEC. 2. SMOKE-FREE ENVIRONMENT POLICY.

The Public Health Service Act is amended by adding the following new title at the end thereof:

"TITLE XXVII--SMOKE-FREE ENVIRONMENTS

"SEC. 2701. SMOKE-FREE ENVIRONMENT POLICY.

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

"(b) Elements of Policy.--Each smoke-free environment policy for a public facility shall--

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

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

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

"(c) Specially Designated Smoking Areas.--A specially designated smoking area meets the requirements of this subsection if:

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

"(2) nonsmoking individuals do not have to enter the area for any purpose; and

"(3) children under the age of 15 are prohibited from entering the area.

"SEC. 2702. CITIZEN ACTIONS.

"(a) In General.--An action may be brought to enforce the requirements of this title by any aggrieved person, any State or local government agency, or the Administrator.

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

"(c) Notice.--An aggrieved person shall give any alleged violator written notice of at least 60 days prior to commencing an action under this section. No action may be commenced by an aggrieved person under this section if such alleged violator complies with the requirements of this title within such 60-day period and thereafter.

"(d) Costs.--The court, in issuing any final order in any action brought pursuant to this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any prevailing party, whenever the court determines such award is appropriate.

"(e) Penalties.--The court in any action under this section to apply civil penalties shall have discretion to order that such civil penalties be used for projects which further the policies of this

title. The court shall obtain the view of the Administrator in exercising such discretion and selecting any such projects.

"(f) Damages.—No damages of any kind, whether compensatory or punitive, shall be awarded in actions brought pursuant to this title.

"(g) Isolated Incidents.—Violations of the prohibition specified in section 2701(b)(1) by an individual within a public facility or on facility property shall not be considered violations of this title on the part of the responsible entity if such violations:

"(1) are isolated incidents that are not part of a pattern of violations of such prohibition; and
"(2) are not authorized by the responsible entity.

"SEC. 2703. PREEMPTION.

"Nothing in this title shall preempt or otherwise affect any other Federal, State or local law which provides protection from health hazards from environmental tobacco smoke.

"SEC. 2704. REGULATIONS.

"The Administrator is authorized to promulgate such regulations as the Administrator deems necessary to carry out this title.

"SEC. 2705. EFFECTIVE DATE.

"The requirements of this title shall take effect on the date one year after the date of the enactment of the Smoke-Free Environment Act of 1993.

"SEC. 2706. DEFINITIONS.

"As used in this title—

"(1) The term 'Administrator' means the Administrator of the Environmental Protection Agency.

"(2) The term 'public facility' means any building regularly entered by 10 or more individuals at least one day per week, including any such building owned by or leased to a Federal, State, or local government entity. Such term shall not include any building or portion thereof regularly used for residential purposes.

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

-waxman\h3434.wri