

THE COMPLETE TEXT OF THE REPORT OF THE KOOP-KESSLER ADVISORY COMMITTEE ON TOBACCO POLICY AND PUBLIC HEALTH [footnotes and appendices omitted, some minor formatting errors]

Presented here by Action on Smoking and Health (ASH), a 30-year old national legal-action antismoking organization which is one of the members of the Advisory Committee.

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 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." 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." 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...

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

- 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. 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.

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

- IMPACT and ASSIST grants 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

- Excise taxes on tobacco products should be dramatically increased and should be indexed to inflation.
- 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. Nicotine, a major constituent of tobacco, is highly addictive and "cigarettes and other forms of tobacco are just as addicting as heroin and cocaine. . . ." 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 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."

- 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 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 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. 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.

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.

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 should 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 consumption and as a means of raising revenues as one source of support 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.

<http://ash.org/areport.html>

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.

	<p>ACTION ON SMOKING AND HEALTH (ASH) 2013 H Street, NW / Washington, DC, 20006 / (202) 659-4310</p> <p><i>A National Legal-Action Antismoking Organization Entirely Supported by Your Tax-Deductible Contributions</i></p> <p>NOW CELEBRATING 30 YEARS OF PUBLIC SERVICE</p> <p>All materials on ASH's main and supplemental web pages may be freely copied and reproduced in print or on other web pages. Please give credit to ASH, and include ASH's web address: http://ash.org/</p>
---	--

**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

Prof. John F. Banzhaf III, J.D., Esq., Executive Director & Chief Counsel

Kathleen E. Scheg, J.D., Esq., Legislative Counsel

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

<http://ash.org/members.html>

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

Eilcen 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

07/11/97

09:23

202 401 7321

HHS ASPE/HP

[ap://ash.org/members.html](http://ash.org/members.html)

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**

Task Force Members**Task Force on the Regulation of Nicotine and Tobacco Products:**

- 1) American Cancer Society (John Seffrin -- Chair)
- 2) National Center for Tobacco-Free Kids (William Novelli/Matthew Myers)
- 3) Stop Teenage Addiction to Tobacco (Judy Sopenski)
- 4) Tobacco Products Liability Project (Richard Daynard)

Task Force on Youth and Tobacco:

<http://ash.org/members.html>

- 1) American Academy of Pediatrics (Richard Heyman -- Chair)
- 2) American Academy of Family Physicians (Robert Graham)
- 3) American Cancer Society (John Seffrin)
- 4) American College of Chest Physicians (Robert McCaffree)
- 5) American Public Health Association (Katherine McCarter for Mohammed Akhter)
- 6) Association of State and Territorial Health Officials (Donald Williamson)
- 7) National Center for Tobacco-Free Kids (William Novelli)
- 8) National Medical Association (Yvonnechris Veal for Randall Morgan)
- 9) Partnership for Prevention (Jonathan Fielding)
- 10) Smokeless States National Program (Thomas Houston)
- 11) Stop Teenage Addition to Tobacco (Judy Sopenski)

Task Force on Current Users of Tobacco Products:

- 1) American Medical Association (Randolph Smoak for Nancy Dickey -- Chair)
- 2) American Academy of Family Physicians (Robert Graham)
- 3) American Academy of Pediatrics (Richard Heyman)
- 4) American College of Chest Physicians (Robert McCaffree)
- 5) American College of Preventive Medicine (George Anderson)
- 6) National Medical Association (Yvonnechris Veal for Randall Morgan)
- 7) The Onyx Group (Jesse Brown)
- 8) Smokeless States National Program (Thomas Houston)

Task Force on Environmental Tobacco Smoke:

- 1) American Lung Association (John Garrison -- Chair)
- 2) Action on Smoking and Health (John Banzhaf)
- 3) American College of Preventive Medicine (George Anderson)
- 4) American Heart Association (Dudley Hafner)
- 5) American Public Health Association (Katherine McCarter for Mohammed Akhter)
- 6) Americans for Non-smokers Rights (Julia Carol)
- 7) Association of State and Territorial Health Officials (Donald Williamson)

Task Force on the Future of the Tobacco Industry and Tobacco Control Efforts:

- 1) Advocacy Institute (Michael Pertschuk -- Chair)
- 2) American Heart Association (Dudley Hafner)
- 3) American Lung Association (John Garrison)
- 4) American Medical Association (Randolph Smoak for Nancy Dickey)
- 5) Americans for Non-smokers Rights (Julia Carol)
- 6) National Center for Tobacco Free Kids (Matthew Myers)
- 7) The Onyx Group (Jesse Brown)
- 8) Partnership for Prevention (Jonathan Fielding)

07/11/97

09:24

202 401 7321

HHS ASPE/HP

<http://ash.org/members.html>

The Advisory Committee on Tobacco Policy and Public Health

Staff to the Committee

Jeff Nesbit, Staff Director

Timothy M. Westmoreland, J.D., Counsel

Ruth J. Katz, J.D., M.P.H., Counsel

Michael D. Beauvais, Legal Associate

R. Scott Foster, J.D., Legal Associate

Susan E. O'Donnell, M.A., Public Affairs

Martha Ross, Senior Program Associate

Mary Supley, Public Affairs

	<p>ACTION ON SMOKING AND HEALTH (ASH) 2013 H Street, NW / Washington, DC, 20006 / (202) 659-4310</p>
	<p><i>A National Legal-Action Antismoking Organization Entirely Supported by Your Tax-Deductible Contributions</i></p> <p>NOW CELEBRATING 30 YEARS OF PUBLIC SERVICE</p> <p>All materials on ASH's main and supplemental web pages may be freely copied and reproduced in print or on other web pages. Please give credit to ASH, and include ASH's web address:</p> <p>http://ash.org/</p>

DRAFT (July 14, 1997)

(Incorporates comments from CDC, Marc Manley/Joe Harford memo, SAMHSA price elasticity info)

TOBACCO-RELATED RESEARCH

Workgroup Report

CONTENTS

Introduction

I. ANALYSIS OF APPLICABLE SETTLEMENT PROVISIONS

- A. Funds Available
- B. Key Questions to Be Addressed and Areas for Potential Modification of Settlement
 - 1) Defining "Tobacco-related"
 - 2) Mechanisms for Decision-making, Investment and Priority Setting
 - 3) Maintenance of Effort Protections
 - 4) Relationship between Tobacco Use Cessation Trust Fund and Public Health Trust Fund.

II. BASELINE: CURRENTLY AVAILABLE SERVICES AND ACTIVITIES

A. Basic Research

- 1) Biomedical
- 2) Clinical
- 3) Behavioral

B. Applied Research

- 1) Health Services
- 2) Public Health & Community
- 3) Surveillance/Epidemiological
- 4) Behavioral

III. GAPS AND NEEDS

A. Basic Research

- 1) Biomedical
- 2) Clinical
- 3) Behavioral

B. Applied Research

- 1) Health Services
- 2) Public Health & Community
- 3) Surveillance/Epidemiological
- 4) Behavioral

IV. OPTIONS FOR SETTLEMENT IMPLEMENTATION AND SPENDING

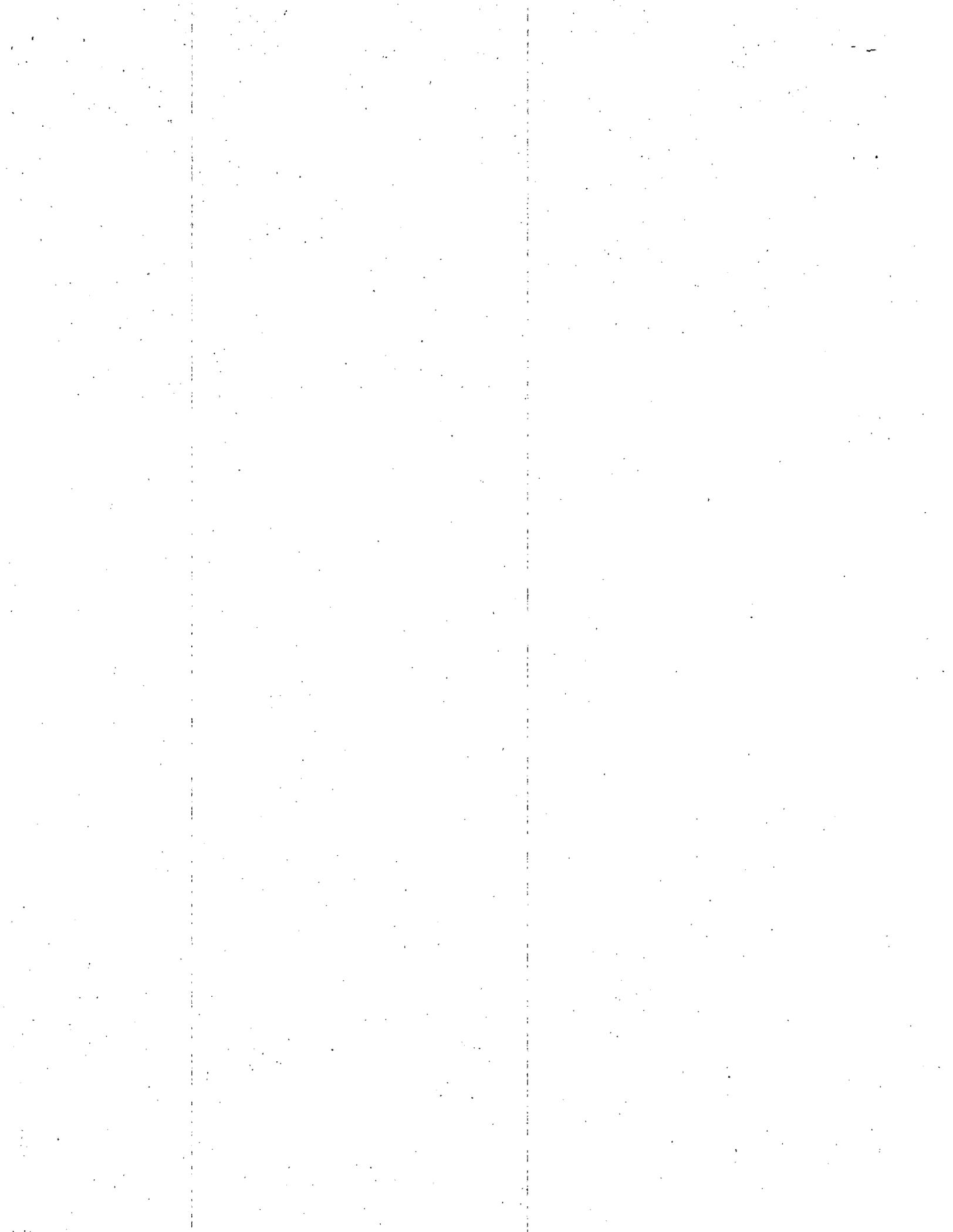
- A. Principles
- B. Funding Strategy

V. SUFFICIENCY OF SETTLEMENT FUNDING

VI. APPROACHES FOR FLOW OF SETTLEMENT FUNDING/OTHER FUNDING MECHANISMS

APPENDICES

NIH Plans for Public Health Trust Fund
Analysis of Tobacco Price Elasticity



Introduction

A robust, comprehensive and well funded tobacco research program is essential to guide and strengthen new policies, regulations, and programs supported by public and private funds. Research must address issues at the national, state, local, and individual level, and must include studies of tobacco use among both youth and adults, and its impact on health, disease and quality of life. Of particular urgency is the need for information to inform rapidly developing federal and state policies and programs of the science and evidence-based findings. As new resources for tobacco control become available from HHS agencies, state governments, and possibly the tobacco industry, research must guide their use.

I. ANALYSIS OF APPLICABLE SETTLEMENT PROVISIONS

A. **Funds Available.** The proposed settlement contains four potential funding sources that could be utilized for health-/tobacco-related research:

1) **Reduction in Tobacco Usage.** \$125 million (years 1-3) and \$225 million annually thereafter would be allocated by HHS to activities designed to reduce tobacco use. Allowable expenditures would include:

- ▶ “research into and development and public dissemination of technologies and methods to reduce the risk of dependence and injury from tobacco product-usage and exposure; and
- ▶ “identification, testing and evaluation of the health effects of both tobacco and non-tobacco constituents of tobacco products.”

2) **Prevention/Cessation Research.** \$100 million annually to fund research and the development of methods for how to discourage individuals from starting to use tobacco and how to help individuals to quit using tobacco.

3) **Tobacco Use Cessation Trust Fund.** \$1 billion in years 1-4 and \$1.5 billion thereafter paid into a trust fund to be used to assist individuals who want to quit using tobacco to do so. Trust fund does not currently allow funds to conduct cessation or evaluation research.

4) **Public Health Trust Fund.** \$25 billion trust fund is established with funding accruing at an increasing rate of \$2.5 billion per year for eight years. Funds are to be used for “tobacco-related medical research” as determined by a Presidential Commission “to include representatives of the public health community, Attorneys General, Castano attorneys and others.”

B. **Key Questions to Be Addressed and Areas for Potential Modification of Settlement**

1) **Defining “Tobacco-related Research.”** There is a concern that tobacco-related research (TRR) identified in the proposed Settlement is inadequately defined. Tobacco-

related research is defined as research related to reducing tobacco use and reducing the burden of diseases caused by tobacco, including scientific investigations into 1) the patterns, determinants, and consequences of tobacco use and exposure to tobacco smoke; 2) the components of tobacco products that promote addiction and disease (including their molecular and genetic effects); 3) the efficacy and effectiveness of interventions designed to prevent initiation, promote cessation, and protect nonsmokers; and 4) ways to improve treatment for persons suffering from nicotine addiction and the diseases caused by tobacco use.

2) Mechanisms for Decisionmaking, Investment and Priority Setting,

Administration. Significant issues surround the Public Health Trust Fund governing structure. Including using the Trust Fund as a mechanism for allocating health research funds.

- ▶ The composition of the board is an issue, including defining the appropriate role of the State Attorney Generals and Castano attorneys with regard to the allocation of research funds.
- ▶ There is a need to clarify the objectives of the Trust Fund and the goals that should guide annual expenditures. Consideration needs to be given to designing the fund to provide needed research funds into perpetuity. To accomplish this annual expenditures should not deplete the initial \$25 billion capital reserve.
- ▶ Consider keeping separate the funding streams for different research areas--if one area of research was shut down or de-emphasized, it should not effect other areas funded through the Trust Fund.
- ▶ Consider issues to protect against supplantation . It is critical that additional funding not be allocated to the general NIH research base and instead be earmarked for specific program areas. A truly comprehensive tobacco control research portfolio will contribute to real reductions in tobacco use only if it is linked closely to ongoing and expanded intervention programs and the findings of cutting edge biomedical research.
- ▶ Productive partnerships with public and private organizations are essential. Funding should be made available not only for the activities of the current NIH national research institutes but also the Agency for Health Care Policy Research which should take the lead in developing more effective delivery mechanisms for cessation services.

3) Maintenance of Effort Protections. Specific protections will be needed to prevent the new research funds from supplanting the Congress' annual appropriation. Settlement funding should be in addition to current appropriations and not reduce Congress' annual

appropriation to the NIH, AHCPR or agencies engaged in tobacco-related research.

4) Relationship between Tobacco Use Cessation Trust Fund and Public Health Trust Fund. It is unclear what, if any, relationship exists between the Cessation and Public Health Trust Funds.

II. BASELINE: CURRENTLY AVAILABLE SERVICES AND ACTIVITIES

[Placeholder: NIH with CDC provide summary of baseline data]

[NIH suggests a narrative descriptions of current research efforts (see Appendix) rather than the following categorization which would necessitate “the arbitrary categorization of literally hundreds of grants,” but that the categories are appropriate for Section III]

Use workgroup framework:

A. Basic:

- 1) Biomedical
- 2) Clinical
- 3) Behavioral

B. Applied

- 1) Health Services
- 2) Public Health & Community
- 3) Surveillance/Epidemiological
- 4) Behavioral

Price Elasticity (Appendix ?): From the literature on the price elasticities of cigarettes this review, the following conservative estimates of price elasticities by age group for cigarettes are shown in the table below. The summarized results are quite robust across studies:

Age Group	Total Elasticity	Smoking Rate	Quantity per Smoker
12-19	-1.2	-0.70	-0.50
20-25	-0.90	-0.55	-0.35
26-35	-0.45	-0.25	-0.20
36-74	-0.40	-0.20	-0.20

Based on these studies, the rate of smoking may be distinguished from the quantity of cigarettes consumed by smokers. For youth smoking rates the reductions result from decisions not to start smoking (reduced initiation rates), while with adult smokers the reductions are due to decisions to quit smoking (quit rates).]

III. GAPS AND NEEDS

A. Basic Research

- 1) **Biomedical:** Including carcinogenesis, pharmacology of addiction, molecular biology, genetics.
- 2) **Clinical:** Including (both behavioral & pharmacological) diagnosis, and prevention, treatment, rehabilitation tobacco-related disease,
- 3) **Behavioral:** Including animal studies (crosses over to applied research), substance abuse, other areas linked to tobacco use (sexual abuse).

Examples of basic research needs:

- ▶ Basic research on product and ingredients; not only nicotine, but other harmful effects of product in ways that may not be obvious.
- ▶ Assessing the health effects of cigar use among youth and adults;
- ▶ Biological processes of tobacco-related disease;
- ▶ Genetic predictors of nicotine addiction and genetic markers of diseases caused by tobacco; and
- ▶ Ways to improve the prevention, diagnosis, and treatment of diseases and disorders caused by tobacco.
- ▶ Research on the impact of developing less hazardous tobacco products; has this and would this ultimately benefit public health? (For example, "light" cigarettes may have actually kept people in the market, increasing prevalence of disease and death.) Crosses over to behavioral and epidemiological research.

B. Applied Research

1. **Health Services:** Including patterns of use (are people getting cessation), access, reimbursement, delivery, patient compliance, implied implementation in health care systems, recidivism in programs, cost and cost effectiveness, and treatment guidelines.
2. **Public Health & Community:** Including research and evaluation of public & private policy, community & state programs and laws, field programs, impact of enforcement, and role of community agencies in affecting advertising policy norms.
3. **Surveillance/Epidemiological:** Including population-based studies of patterns and determinants of tobacco use behaviors (including initiation, cessation, nicotine dependence, brand preference, and product selection) and environmental tobacco smoke (ETS) exposure; laboratory work on the product (e.g., identifying added chemicals); studies of the prevalence of policies and legislation regarding tobacco-use; and studies of tobacco use as a risk factor for disease and addiction.

4. Behavioral: social processes and modeling, developmental risk factors (e.g., prenatal exposures), animal studies, research on addiction and craving, effects of pricing (behavioral economics), health behavior and attitude, pre-disposal, determinants of initiation, community, behavioral intervention, studies of nicotine as a “gateway”, prevention, and effect on special populations.

Examples of applied research needs:

- ▶ Monitoring of product and ingredients, including nicotine, but other harmful effects of product, including ETS.
- ▶ Tobacco industry “culture change.”
- ▶ State and community program implementation; clean indoor air laws, excise tax increases, advertising restrictions, youth access restrictions.
- ▶ Product and ingredient monitoring.
- ▶ Industry product marketing and distribution practices (and changes) as a result of differences (and changes) in Federal and state excise taxes.
- ▶ Efficacy of current and planned control efforts & enforcement efforts.
- ▶ New, proposed, and future regulations, e.g., reducing nicotine content of cigarettes; evaluating technologies to reduce the health risk of tobacco products.
- ▶ Racial, cultural, and gender influences in youth tobacco use.
- ▶ Health services research targeted to improving the effectiveness and the delivery of tobacco cessation programs.
- ▶ Assessing the impact of tobacco use on the economy and health care system (time missed from work, cost of premature death, burden of disease on health care costs).
- ▶ Studies of women to establish differential price elasticities for men and women.
- ▶ Estimates for the effect of introduction of lower priced generic brands of tobacco in the marketplace following a tax increase

IV. OPTIONS FOR SETTLEMENT IMPLEMENTATION AND SPENDING

A. Priorities. Consideration of areas for research funded by the Settlement, as well as priority setting within those areas should be guided by two overriding principles. Such research should contribute to a science and knowledge base which would:

- ▶ reduce tobacco use, and
- ▶ reduce the burden of disease on society caused by tobacco use.

[Placeholder: workgroup to consider Robert Wood Johnson (RWJ) portfolio: RWJ’s research portfolio currently includes 42 funded projects (totaling more than \$5.6 million annually). These projects deal primarily with topics related to health-policy research, especially in the areas we have defined as Public Health and Community, Behavioral, Health Services Research, and Surveillance and Epidemiology.]

In addition, there will be an important need for evaluation of the Settlement, e.g., impact of warning labels, litigation, penalties, etc. An overall evaluation would be very complex.

- B. Funding Strategy.** Consideration should be given to the principle which would provide half of the available funding for basic research and the other half for applied research, as defined elsewhere in this document. [Need more discussion on logic.]

[Placeholder: other principles?: research which contributes to improving the effectiveness of state and local tobacco control programs and their components;

V. SUFFICIENCY OF SETTLEMENT FUNDING

In consideration of the serious needs and gaps in current research efforts, the funding level is inadequate.

One approach is to view the funding for research commensurate with the toll that tobacco related disease places on the disease burden of the American people. Tobacco-related disease represents a major burden on the NIH research agenda. A settlement with the tobacco industry should provide NIH with an annual supplemental payment commensurate with that burden.

The National Cancer Institute currently spends only \$70 million of its \$2 billion annual appropriation for tobacco-related medical research. Yet tobacco use is responsible for 30 percent of the cancer incidence, one-third of cardiovascular disease deaths and 90 percent of chronic obstructive pulmonary disease. Science continues to identify additional diseases (SIDS, low-birth weight babies, miscarriage, and birth defects such as cleft lip and palate, and periodontal disease) where tobacco use is implicated.

Given the magnitude of tobacco use as a public health problem, the many new programs and regulations proposed in the settlement, and the scientific opportunities we know exist, consideration should be given to a more appropriate budget "supplement" for tobacco related health research should be in the range of \$2-4 billion annually. These funds should be in addition to whatever funds are allocated to tobacco cessation programs.

VI. APPROACHES FOR FLOW OF SETTLEMENT FUNDING/OTHER FUNDING MECHANISMS

[Placeholder: 50/50 split discussion]

Consideration should be given to using an existing Congressionally established mechanism such as the existing NIH National Foundation for Biomedical Research, or the establishment of a new entity modeled after the Department of Defense's Jackson Foundation.

Appendix (?)

Analysis of Tobacco Price Elasticity Research

From the literature on the price elasticities of cigarettes this review, the following conservative estimates of price elasticities by age group for cigarettes are shown in the table below. The summarized results are quite robust across studies:

Age Group	Total Elasticity	Smoking Rate	Quantity per Smoker
12-19	-1.2	-0.70	-0.50
20-25	-0.90	-0.55	-0.35
26-35	-0.45	-0.25	-0.20
36-74	-0.40	-0.20	-0.20

Based on these studies, the rate of smoking may be distinguished from the quantity of cigarettes consumed by smokers. For youth smoking rates the reductions result from decisions not to start smoking (reduced initiation rates), while with adult smokers the reductions are due to decisions to quit smoking (quit rates).

For smokeless tobacco, the price elasticity for those in high school is -0.60 (-0.40 for smoking rate and -0.20 for smoking quantity). For older groups, no studies are available, but based on the age-price elasticities for cigarettes we estimate the price elasticities for smokeless tobacco to be -0.55 for those 20-25 and -0.35 for those 26 and older. Researchers note that an increase in cigarette taxes, without a commensurate increase in taxes on smokeless tobacco, leads to an increase in use of smokeless tobacco.

Additional findings include:

- ▶ The projected elasticities are based on a percentage increase in tobacco prices. As tobacco taxes are unit based and not price based, the effect of tobacco tax increases is impacted by tobacco industry decisions regarding tax "pass through" policies on price and on "erosion" over time because of increases in the CPI. Overall, the percentage increase in tobacco prices due to tobacco taxes will likely diminish over time, with resultant diminished effects in the projected elasticities.
- ▶ Short-term effects (within 1 year) differ from long-term effects (within 3 years). When the increase in price is long-term, the elasticity is found to be greater. For example, for adults, the elasticity in the first year following a tax increase is -0.30, but after 3 years the elasticity increases to -0.60.
- ▶ Education and/or income appear to impact elasticities. Those with higher education/income are unresponsive to price, while those with lower education/income are more responsive to price (-0.60).

- ▶ There are presently too few studies of women to establish differential price elasticities for men and women.
- ▶ The studies establish that price differentials between a state and neighboring states may be an important determinant of demand. For most states, however, this variable does not have a substantial effect.
- ▶ One study finds that as price goes up, smokers substitute toward higher nicotine cigarettes. While this implies that the price effect on quantity smoked would overstate the expected health benefits of reductions in smoking quantity, it does not alter the expected changes in initiation and quit rates.
- ▶ The studies do not provide estimates for the effect of introduction of lower priced generic brands of tobacco in the marketplace following a tax increase.

As a final note, there is evidence that the tobacco industry has been creative in reducing the impact of mandated price increases on the actual price of tobacco paid by the consumer. Therefore, the price elasticities provided above, while based on the research to date, are overly optimistic, especially as to long-term effects. Related research and modeling have been performed in the area of alcohol pricing and elasticity which supports these conclusions. This research has shown that projected price effects over time were overstated, and significant reductions in effects had to be factored for the model to successfully project historical patterns.

**NIH Plans for the Public Health Trust Fund
for Research on Tobacco Use and Tobacco-Related Disease**

[placeholder]

CESSATION/EDUCATION MEETING - JULY 9

CESSATION

Questions

Should we do a big federal program or encourage people to use private programs?

- obviously costs less to let private do it
- if we actually can increase demand for programs, private will most likely respond to that
- we can also create demand by going after employers who buy coverage
- by educating, we don't risk supplanting current state or private cessation programs (ec talk - offer a public good)
- Republican Congress likes priv. vs. public bureaucracy
- Possible Problem - companies may try to hook people on the programs so they can make more money (disincentive to actually cure them?)
- we may want to expand Medicaid or Medicare to cover cessation, but need to do cost #'s

How much does it cost to quit?

- there was a number quoted for nicotine replacement cigarettes as \$65 a month
- still looking for more #'s

Does cessation work?

- the approximate success rate of cessation programs is 10 percent
- if we spend on research first...we may get more in return
- Access to cessation programs does not equal results. Most people quit because of will power. We need to change attitudes and getting people to want to

quit.

How effective is Massachusetts's and California's programs?

- they are comprehensive...we got some info from Mass today via fax

What about Youth Cessation?

- it is presently rare and there is a definite need for it
- tough to study because tough to get teens into labs
- addiction looks similar to adult addiction after 2-3 years
- treatment methods for kids should be different (group therapy no good)
- school based education mixed w/ cessation may work

POSSIBLE STRATEGY

There is an overlap with education and cessation, so we can educate/encourage people to quit smoking, as well as try to prevent adolescents from starting. We should also spend money on

researching how to effectively stop smoking, and maybe transfer that money to implementing the programs once we determine what's best.

EDUCATION

ASSIST (Mark Manley)

ASSIST is a 17-state tobacco control demo run by the National Cancer Institute. It costs an average of \$1.2 million per state. ASSIST is most effective in setting up anti-smoking infrastructure and building coalitions and networks among businesss, state and local governments, and interest groups. It gives the movement a voice in major meetings and makes sure that the issue remains on the table. It currently does not fund much more than general staff things. Some states choose to use other resources to fund more extensive programs, most notably Massachusetts and California, which fund massive anti-smoking campaigns with excise taxes. (MA is an ASSIST state, CA isn't.) The results seem promisi, cutting consumption rates by an average of 7 percent. (Massachusetts has a drop of about 28 percent...but the cigarette tax may have a lot to do with this)

EDUCATION CAMPAIGN (CDC guy)

- 1- \$500 million is a reasonable number for a nationwide campaign
 - if Mass. was implemented nationwide, it would cost at least \$600 million
- 2- Campaign management - national, state, and local should all work together
 - may be easier to buy media nationwide (kids may repond better to this too)
 - follow up and drive it home with local events & schools, etc.
 - schools, media, community all complement each other
 - the event sponsership replacement provision will primarily go to small venues