CDC's Proposed Public Health Initiative

Resources potentially resulting from the tobacco settlement should be used for unmet public health needs. We propose using the settlement dollars in three high priority areas:

I. Implement Known and Effective Prevention Strategies for Youth ($550 million)

- **School-based Health Education:** This initiative would implement comprehensive school health programs in every State in the Nation and develop and disseminate model policies and programs through national partners. ($100 million)

- **Tobacco:** The initiative would implement a comprehensive approach to tobacco use prevention and substantially strengthen state-based tobacco efforts. ($230 million)

- **Other important youth priorities** ($220 million)
  - Safe America: Through Injury Prevention and Control
  - Healthy Homes, Healthy Children
  - Hazardous Chemical Exposures in Children
  - Prevention of STD-related infertility in youth

II. Develop and Address Unmet Opportunities for Prevention ($290 million)

- **Cardiovascular Disease:** No national public health program addresses this major cause of tobacco-related death. This initiative would establish that capacity in all States. ($100 million)

- **Monitor the Health of the Nation:** It is vital to have in place adequate health information systems to monitor the impact of public health efforts. CDC and the States do not have the capacity to do this. This initiative would build it. ($120 million)

- **Other Priorities** ($70 million)
  - Asthma prevention
  - Capacity for Occupational Safety and Health
  - Folic Acid for Healthy Babies and Adults

III. Protect Public Health: Repair Past Damage and Prepare for Urgent Threats ($520 million)

- **Prevention Block Grant:** Public health has eroded over the last two decades, as reported by the IOM. Doubling the prevention block grant would repair that erosion and direct resources to States to use as they see fit to address public health needs. ($150 million)

- **Infectious Diseases: Emerging and Reemerging Threats:** Infectious diseases are the third leading cause of death in the United States. This initiative would implement "A Prevention Strategy for the United States." ($120 million)

- **Other Priorities** ($250 million)
  - Vaccine-preventable Diseases
  - Emergency Preparedness
  - Preventing Environmental Disease

DRAFT (July 14, 1997)
(Incorporates comments from CDC, Marc Manley/Joe Harford memo, SAMHSA price elasticity info)

TOBACCO-RELATED RESEARCH
Workgroup Report

CONTENTS

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 form 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 a 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]

July 11, 1997

Attached is the first rough draft of the Tobacco-Related Research workgroup report. Please provide me changes, comments, and other input on all aspects of the draft, including the report outline/format. If I'm not available, feel free to provide input to Dr. Lynn Cates, (202) 690-7996.

If you have any downloading problems call Nicole Lawrence, (202) 690-6870, and she'll fax you a copy.

Please let me know if you will be involved in the subgroup drafting the next draft and final report (if possible, before Monday's meeting). Subsequent drafting will probably involve carving-up the document and assigning sections to different offices.

Thanks.

Burke Fishburn
(202) 690-7807
bfishbur@osaspe.dhhs.gov

DRAFT (July 10, 1997)

TOBACCO-RELATED RESEARCH
Workgroup Report

CONTENTS

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 adult tobacco use and its impact on youth. Of particular urgency is the need for information to inform federal and state policies and programs that are under development. As new resources for tobacco control become available from HHS agencies, state governments, and possibly the tobacco industry, research must guide their use.

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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. TRR should broadly represent a comprehensive research portfolio including basic biomedical research, health services research, and tobacco-related control interventions. Any agreement needs to appropriately divide available funding between basic biomedical research areas and tobacco-related prevention (including health services research).

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.

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appropriations and not reduce Congress' annual appropriation to the NIH, AHCPR or agencies engaged in tobacco-related research.

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II. BASELINE: CURRENTLY AVAILABLE SERVICES AND ACTIVITIES

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

[Use workgroup framework:
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2) Clinical
3) Behavioral

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4) Behavioral]

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 treatment of diseases 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 laboratory work on the product (e.g., what chemicals are added?) ETS, trends in use, attitudes toward use, trends in initiation, trends in policies, and quitting trends.

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.
- Product distribution changed as a result of current differences and changes Federal 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 form work, cost of premature death, burden of disease on health care costs).

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]

In addition, there will be a 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) 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.

DRAFT (July 9, 1997)

SMOKING CESSATION & PUBLIC EDUCATION

Workgroup Report

CONTENTS

Introduction

There are three prongs to this issue, preventing and deterring people from starting to smoke, cessation and protecting non-smokers. Therefore, public education should be treated as an integral component of any approaches designed to reduce the use of tobacco products.

There are approximately 50 million smokers and 70 percent say they would like to quit; of those, 10 percent seriously attempt to quit, of which 20 percent actually succeed. The Settlement provides substantial funds to help them do so.

Cessation strategies must take into account that smoking is an addiction. It should not be anticipated that success rates for cessation treatments will be as high or as easy to measure as those for more acute processes (e.g., antibiotic treatment for infections). Instead, cessation programs should be regarded in the same light as other chronic conditions such as diabetes, and their success should be held to realistic standards.

[Placeholder: summary of data on cost of quitting, average number of times it takes the average person to quit (on their own, product-assisted, behavioral intervention, enter health care system).]

[Placeholder: summary of data on what is known about the effectiveness of cessation and education programs.]

I. ANALYSIS OF APPLICABLE SETTLEMENT PROVISIONS

A. Funds Available. The Settlement does not provide prescriptive detail on how the money is to be spent on cessation and education activities, particularly, given the amounts of the allocations. The funding streams specified for cessatiopn and education actiovities include the following:

- ***Reduction in Tobacco Usage ($5.325 billion)***: For Secretary of HHS to encourage current tobacco users to quit through media-based and non-media based education, prevention and cessation campaigns.

- ***Programs like ASSIST ($3.0 billion)***: For state and local tobacco control, similar to the community-based model of the ASSIST program

- ***Education ($12.5 billion)***: To fund an Independent, non-profit organization to run a multi-media campaign to discourage and de-glamorize tobacco use.

- ***Cessation Fund ($35.5 billion)***: To create a trust fund to promote effective cessation programs and provide financial assistance to access such programs. $1 billion per year for 4 years, and then $1.5 billion per year to assist cessation for those who want to stop using tobacco products

There also is the potential for crossover with two other funds: the Teams' Fund and the

Public Health Trust Fund.

- ***Teams' Fund ($1.8 billion)***: For 10 years, to compensate events, teams, or entries in such events who lose sponsorship by the tobacco industry as a result of the Settlement. After 10 years, funds will be reallocated to education, enforcement of provisions, and community-based programs.

- ***Public Health Trust Fund ($25 billion)***: A Presidential Commission will be created to identify and fund specific tobacco-related medical research.

B. Implementation of Settlement

1) **Mechanism of administration of Settlement funds.** [Placeholder: Analysis of Settlement's wording re: Secretary's responsibilities]

2) **Permissible use of Settlement funds.** [Placeholder: Analysis of programs provided for in Settlement]

3) **Restrictions on use of Settlement funds.** [Placeholder: Analysis of restrictions on use of Settlement funds]

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

1). **Mechanisms for Decision-making, Investment and Priority Setting.** Possibilities include government, nonprofit, or a combination of different mechanisms.

2) **Mechanisms for Administration of Settlement Funds.** Possibilities include government, nonprofit, or a combination of different mechanisms. The funds could be allocated into separate and distinct pots for management and distribution, or commingled in certain areas. There are pros and cons of each approach.

3) **Monitoring and Surveillance Systems**

4) **Investments in Current Mechanisms and Development of New Strategies.** Priority should be given to strategies targeting adolescents

5) **Appropriate Allocation of Resources for Cessation to Indian Tribes.** The Settlement treats tribes like states, but the formula is based on tribal population as a percentage of state population, thus not providing adequate

funds for successful program implementation

II. BASELINE: CURRENTLY AVAILABLE SERVICES AND ACTIVITIES

NIH ASSIST and CDC IMPACT programs have created the infrastructure for broader cessation and education program implementation. They permit local input, assuring that programs are tailored to local needs. The current ASSIST budget is $1.2 million per year per state in 17 states. This level of funding is considered to be bare bones. The success of at least some of the programs is the result of certain states' voluntarily providing matching funds. Even so, the funds are not always sufficient to provide services throughout the state.

A. Public Programs

1) **Public Cessation Programs.** [Placeholder: GAO study on/summary of all cessation programs.]

a. ASSIST and IMPACT. Summary of NIH ASSIST and CDC IMPACT cessation activities.

[Summary and reference to CDC document--attachment.] CDC analysis of state spending for cessation programs ranges from $0.11 to $11.00 per capita, with a clear dose-response relationship (i.e., states with the biggest investments like California and Massachusetts have had the most success in reducing smoking).

b. AHCPR Guidelines. [Summary and reference to AHCPR cessation document--attachment.] AHCPR has smoking cessation guidelines and is evaluating implementation and cost-effectiveness.

c. Medicare/Medicaid. Six states' Medicaid programs reimburse for some cessation services. [Placeholder: what percentage of Medicaid patients are accessing programs/benefits.]

No cessation benefits are funded by Medicare

d. Federal/State Excise Tax. [Placeholder: data on impact on cessation of price increases such as excise taxes (adult, youth, "rational addiction")]

2) **Public Education Programs**. [Placeholder: Reference CDC document on education/media] and [Placeholder: summary of data state and local program including schools]

B. **Private and Non-profit Cessation and Education Programs**. Currently, if any cessation benefits are provided at all by insurance companies or managed care organizations, there are limits (e.g., eligibility, co-pays, number of visits, payment contingent on smoker's actually quitting or having not smoked for 6 months, etc.).

[Placeholder: analysis of NGO investments in media messages]

[Placeholder: More data/analysis needed here]

III. GAPS AND NEEDS

A. **Access**. We need to increase our ability to reach the people who need help when they want it. It has been hard to get people into intensive treatment, and the reasons have not yet been well-defined, but are felt to include the lack of availability of programs when they are ready to use them and/or, if programs are available, the complicated procedures required to enter them.

Additionally, there is concern that minorities and lower-income people cannot afford currently available or future strategies to stop smoking (e.g., cost of nicotine-replacement without counseling is approximately $500-600 per person)

[Placeholder: analysis of Medicare provided coverage of cessation programs, all states cover through Medicaid.]

B. **Cost-Effectiveness of Cessation Program Expansion**. There is some evidence that although it costs more to provide cessation services to more individuals, after a certain point there is an economy of scale, and costs per individual begin to decrease so that the overall program is more cost-effective (i.e., the higher the investment, the more return you probably will see per dollar invested).

C. **Continuous Funding of Current Efforts Is Not Guaranteed**. The ASSIST program currently has a budget of $1.2 million per state for 17 states, but this funding will end in 1999. If it is not refunded, an important infrastructure will be lost.

D. **Perception of Cessation Programs**. Cessation programs are perceived by some to be ineffective and there has been criticism of spending money on programs that have not been demonstrated to be effective. It needs to be made clear that treatment for tobacco addiction will not have the same success rate as antibiotic therapy for infections, and that this problem needs to be perceived and managed with approaches comparable for those for chronic diseases such as diabetes.

E. **Advertising**. The current advertising market needs to be analyzed with regard to strategies and cost.

1) **Advertising strategies**. Some research has been performed evaluating effectiveness of media messages and advertising campaigns and, as a result of analysis done for the FDA tobacco rule, information has become available about what is necessary to penetrate target markets. Any use of media in cessation campaigns needs to be comprehensive and not just include strategies that traditionally come to mind first, such as TV and radio advertising. Successful marketing strategies of tobacco companies and other industries (e.g., Levi Strauss and Nike) should be examined for their applicability.

2) **Advertising costs.** One nicotine-replacement manufacturer spends an estimated $120 million per year on advertising for a nicotine-replacement product. If the successful media campaign currently being employed by the state of Massachusetts were expanded to the entire nation, the estimated cost would be approximately $600 million ? per year. However, in order to achieve the same success rates, national programs would probably be more expensive because Massachusetts is a relatively homogenous state and national strategies would have to take into account more ethnic and cultural diversity. In addition to any national effort, it will be critical that states have discretionary funds to provide appropriately targeted local.

E. **Evaluation**. Monitoring and evaluation of efficacy of current and proposed efforts have been inadequate to date.

F. **Eligibility**. Requirements for benefits are unclear. [Need data]

G. **Provider education**. There is no organized or comprehensive nationwide approach for clinicians (including physicians, nurses, hospitals, health plans, etc). Such efforts could be designed along the lines of AHCPR's 2/3 campaign.

H. **Research on Alternatives to Current Cessation Strategies**.

I. **Affordability**.

IV. SETTLEMENT IMPLEMENTATION AND SPENDING APPROACHES

A. Priorities

1) **Education & Assistance -vs- Service Delivery**. There is an issue about whether to use funds to invest in areas (education and assistance) that create demand for cessation services/products, or on service delivery or programs that are or could/should be provided by others (particularly the private sector). In areas where we do fund services, those services should be targeted at specific subpopulations. Regardless, we needs strategies to encourage the private sector to deliver cessation products/programs/services.

2) **Youth Programs**. Need to develop effective cessation programs for youth (controversial, e.g., use of nicotine replacement products).

3) **Access**. Develop better ways for people who want to stop smoking to get into programs (e.g., 1-800- phone number to hotline on each pack of cigarettes, or well-advertised hot lines such as those successfully implemented in California which provide counseling and make referrals)

4) **Clinician Education**. Some portion of cessation and education money needs to go to teach clinicians (nurses and doctors) and managed care plans as to how to encourage smoking cessation.

5) **Matching Funds**. Whenever possible means to provide matching funds for private or local initiative should be employed, instead of creating and funding entire programs in order to help stretch Settlement dollars (e.g., by reaching more individuals and/or eliminating current limits), encourage innovative new strategies, and complement current work without supplanting it. Careful limits should be set for the kinds of work that will be funded (e.g., in planning ASSIST, it was determined that the program would not pay for cessation, but would educate to stimulate a demand for smoking cessation services that is filled by the private sector). This could use Medicaid/Medicare as a model)

6) **Public/Private Partnerships**. Develop partnerships (intergovernmental and public/private) whenever feasible disseminate information and provide services.

7) **Education Campaigns**. Implement new educational and public relations campaigns

8) **Non-nicotine Replacement Techniques**. Implement results of promising research on non-nicotine replacement techniques that currently are under study.

9) **Eligibility**. Define eligibility requirements for (Federally supported) services.

B. Research Agenda

1) **Pursue Innovative Strategies for Prevention and Cessation**. Study replacement products (other than nicotine-replacement) as well as social and psychological methods.

2) **Market Analysis of Successful Private Sector Cessation Programs/products**. Government does not necessarily need to deliver cessation products and services itself, since successful prevention and cessation education campaigns may create a market for cessation services sufficient to attract private investment (e.g., nicotine-replacement). Market analysis is needed to test this hypothesis.

3) **Analysis of Affordability.** Can youth, minorities and lower socioeconomic groups (i.e., those populations at highest risk) afford nicotine-replacement and other smoking cessation products or strategies as they are developed?

V. SUFFICIENCY OF SETTLEMENT FUNDING

[Need some analysis and fact-checking here]

Not enough funding if all smokers who want to quit do it at the same time. (e.g., need a minimum of $500-600 per person for nicotine replacement, without considering counseling - this Settlement provides only $100 per person)

If there are 50 million smokers who all want to quit at one time at a cost of $1000 per smoker, it would cost $50 billion. However, if assumptions are relaxed to reflect more likely scenario that not all smokers would desire to quit right away, then the amount provided in the Settlement is not necessarily inadequate, particularly when the decreasing numbers of new smokers are taken into consideration. It must be borne in mind that, most likely, we will not be having to pay all costs for cessation for each smoker - that many of the costs are incurred by the smoker, or are free (e.g., strong enough desire to quit without formal therapy or other intervention)

Would need a total of $2 million per state per year to fund an ASSIST-like program (which currently covers 17 states (coupled with IMPACT all states and D.C.?). Therefore, $125 million would be sufficient) - even at that, it would only budget pennies per capita, and successful programs like California and Massachusetts provide several ($11) dollars per capita. However, this would fund only a portion cessation intervention programs--the money would be leverage for state (and private?) matching funds.

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

A. **National Insurance Program**. A national program could insure one population (smokers) for one indication (smoking cessation).

B. **Increased Funding to Medicaid and Medicare**. Funds could be applied to smoking cessation benefits. Currently only 6 states have funding for smoking cessation under Medicaid, and none under Medicare.

C. **Private Nonprofit Entity**. This organization could to manage funds at the national level with funding flows to state and local levels. The ASSIST/IMPACT infrastructure and funding could be used for a national campaign coordinated with a strong state and local component.

TOBACCO SETTLEMENT MEETING
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