FOIA Number: 2008-1524-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: Office of Science and Technology Policy

Series/Staff Member: Jerold Mande

Subseries:

OA/ID Number: 13037

FolderID:

Folder Title:
Tobacco Programs/Budget [1]

Stack:	Row:	Section:	Shelf:	Position:
S	66	4	3	3

TOBACCO SETTLEMENT PROGRAM & BUDGET GROUP

DRAFT; AUGUST 29

I. OVERVIEW OF SETTLEMENT

The Program and Budget Group is responsible for (1) evaluating the Settlement's spending recommendations and (2) suggesting explicit changes and options to strengthen spending priorities. The goal is to ensure that funds from the Settlement are invested wisely to improve our understanding of tobacco-related illness, prevent children from smoking, help those that do smoke quit, and provide needed investments in expanded health insurance coverage and public health that were preempted by the excessive costs of tobacco-induced illness.

The proposed settlement divides the spending into four main categories: (1) research, (2) cessation / education, (3) miscellaneous and (4) health investments.

RESEARCH

- **Public Health Trust Fund:** To be used for tobacco-related medical research as determined by a Presidential commission to include representatives from the public health community, Attorneys General, Castano attorneys and others

- **Prevention/cessation research**: To fund research and the development of methods for how to prevent and discourage individuals from starting to use tobacco and how to help individuals quit using tobacco.

CESSATION / EDUCATION

- **Reduction in tobacco usage:** For the Secretary of DHHS to reduce tobacco use through media-based and non-media based education, prevention, and cessation campaigns.

- **Programs like ASSIST**: For community-based state and local tobacco control efforts, similar to the model of the ASSIST program, designed to encourage community involvement in reducing tobacco use.

- **Public education**: For multi-media campaigns run by an independent, non-profit organization to discourage and de-glamorize tobacco use.

- **Tobacco use cessation fund**: For a trust fund to promote effective cessation programs and devices and to enable tobacco users to get assistance in their efforts to quit.

MISCELLANEOUS

- **Up-front commitment:** $10 billion cash payment, payable on statute signing date.

- **FDA enforcement:** To carry out FDA's obligations under and to enforce the terms of the Settlement, including grants to states to assist in enforcement.

- **Teams fund**: For 10 years, to compensate events, teams or entries in such events who lose sponsorship by the tobacco industry. After 10 years, any unused funds will be reallocated to public education, FDA enforcement, and community-based programs.

- **Civil liabilities:** Up to 33 percent of the base payments for judgements/settlements.

HEALTH INVESTMENTS

- **Remaining funds**: The Settlement allows the remaining funds to be used by Federal and/or state governments for high-priority health care initiatives. Although initially intended for children's coverage, the passage of the Budget opens this up to other options.

TOBACCO SETTLEMENT'S SPENDING (Dollars in millions)

	Year One	Five-Year Total	25-Year Total
RESEARCH			
Public Health Trust Fund (research)	2,500	17,500	25,000
Research on cessation	100	500	2,500
CESSATION / EDUCATION			
Reduction in tobacco use	125	825	5,325
State programs / ASSIST	75	500	3,000
Education	500	2,500	12,500
Cessation Trust Fund	1,000	5,500	35,500
MISCELLANEOUS			
Up-front payment	10,000	10,000	10,000
FDA enforcement costs	300	1,500	7,500
Teams' fund	0	300	1,800
Civil liabilities (33%)	[OMB]	[OMB]	[OMB]
Assumed reductions in spending (volume adj., BBA tobacco tax, budget offsets)*	[OMB]	[OMB]	[OMB]
HEALTH INVESTMENTS			
Available funds*	[OMB]	[OMB]	[OMB]
TOTAL	**18,500**	**68,500**	**368,500**

Note: The Settlement provides for an inflation adjustment (not shown here).
* OMB assumes that 25 percent indirect business tax offset. The volume adjuster reduces industry payments in proportion to reduced volume of tobacco sales. The Balanced Budget Act reduced the Settlement by the revenue from the 20-cent tobacco tax. All three are subtracted from funds for health investment.

The following sections summarize recommendations and options related to the Settlement's budget provisions.

A. RESEARCH

The Settlement would establish a $25 billion Public Health Trust Fund to be used for research to find ways to reduce tobacco use and address the enormous burden of diseases caused by tobacco. It would help answer important questions including, but not limited to, identifying how to ensure that children do not start smoking, preventing tobacco-related diseases in current and former smokers, and assessing the genetic influences of tobacco.

The $25 billion, which is allocated over 10 rather than 25 years, would represent a major increase in research funding. It would be established outside of the discretionary caps — an advantage over trying to increase research funding within the discretionary budget where any increase reduces spending for other priorities like education. The Settlement includes few guidelines for this trust fund's structure and operation, leaving the Administration and the Congress the discretion to make such decisions.

The Budget Group agrees on the guiding principles for the trust fund. Its funds should: (1) be distributed on a scientifically objective basis; (2) be used for tobacco-related research, defined as research related to reducing tobacco use and the burden of disease on society caused by tobacco; and (3) supplement not supplant existing research funding. The trust fund would be used for six primary areas of research: biomedical, clinical, behavioral, health services, public health and community, and surveillance/epidemiology. The Presidentially-appointed board overseeing the trust fund would represent scientific experts and members of general public with expertise in areas like public health, basic biomedical research, and health policy. The [four] unresolved issues include:

- **Timing of funds:** The Settlement would gradually make payments to the trust fund over 10 years. To maximize the amount of investment and interest income, DHHS [and OMB?] recommend that the $25 billion be allocated over three years rather than 10 years ($10 billion in the first two years and $5 billion in the third year). Such an endowment fund would generate about $1 billion growing to $3.5 billion in annual interest and investment income for continuous rather than time-limited support for research. While front-loading the payments would better secure stable, long-term funding, it represents a departure from the initial tobacco settlement. The industry may object to this aggressive payment schedule.

- **Administration of investment:** [WORKING GROUP ISSUE] The Settlement appropriately does not specify how the trust fund dollars would be distributed. The trust fund could distribute its funds by serving as a direct granting foundation or by allocating blocks of funds to existing grant agencies (i.e. NIH, CDC). The advantage of direct granting authority is that its funds would not be linked to specific agencies, limiting the likelihood that Congress would reduce these agencies' appropriation accordingly. Allowing direct grant making authority also improves coordination of the entire research agenda since one board, rather than multiple agencies, would determine priorities. However, there is also an advantage to using the existing efficiencies, management, and priority-setting mechanisms in Federal granting agencies. This would decrease the need for a new infrastructure to administer the trust fund research. [recommendations?]

- **Funding priorities:** [WORKING GROUP ISSUE] The research agenda for the trust fund could be set by: (1) allocating specified percentages of the total to the six priority areas outlined above or (2) funding projects solely based on their scientific merit. Having pre-established percentages would ensure that all areas essential to the objectives of the trust fund are adequately funded. However, this might prevent the trust fund from modifying priorities over time or supporting promising research that exceeds the pre-determined percentage allocation.

- **Special funds for surveillance:** [WORKING GROUP ISSUE] Monitoring changes in tobacco prevention and control is critical to enforcing the terms of the Settlement and evaluating the interventions it funds. However, dollars directed toward surveillance reduce the amount available for research. HHS [and OMB?] recommend that some amount of the Public Health Trust Fund be dedicated to surveillance, separate from the rest of the research agenda. [questions: how much money/ what percent?]

RESEARCH FUNDING
(Dollars in Millions; Settlement Amounts Not Inflation of Volume Adjusted)

Budget Line	Year One			Five-Year Total		25-Year Total	
	Baseline	Settlement	DHHS	Settlement	DHHS	Settlement	DHHS
Public Health Trust Fund	1,300*	2,500	10,000	17,500	25,000	25,000	25,000
Cessation Research	na	100	100	500	500	2,500	2,500
TOTAL	1,300	2,600	10,100	18,000	25,500	27,500	27,500

*OMB's estimate of current spending on tobacco-related research
NOTE: Under DHHS recommendations, the funds from the settlement would be invested so that the annual expenditures would come from interest on the investment — an estimated $1 billion annually.

B. CESSATION / EDUCATION

Cessation and prevention initiatives can make meaningful reductions in tobacco use. Prevention programs, especially those based in schools, have proven effective. There is a great need for a media campaign to counter the millions of dollars the tobacco company has used to sell tobacco. And, expanding and supporting effective programs could help the millions of smokers who say they want to quit to do so.

The Settlement proposes that funds be allocated to four different places for cessation and education efforts: DHHS for tobacco use reduction programs; states and communities to fund programs like ASSIST; an independent organization to operate an education campaign; and a trust fund to pay for cessation. The Budget Group believes that coordination across these efforts is critical; that a balance should be maintained between the media campaign, public education, and cessation programs; that funding remain flexible enough to adapt to future changes in effectiveness of interventions; and that services and programs should be directed at adults as well as children. [note: HHS: are there specific recommendations on coordination?]

On the whole, DHHS believes that the funding in cessation and education is adequate. However, the funds might be better allocated across types of efforts. Specifically:

- **Funding for state programs:** State and community-based programs like ASSIST (a comprehensive tobacco use prevention and control program) have proven effective. The proposed funding, however, is not consistent with the levels of funding in successful states like California and Massachusetts. On an annual basis, DHHS recommends that the funds should be increased from $75 million per year to $465 million, composed of:

    - $360 million for state/local infrastructure & programs
    - $85 million for local special grant projects
    - $20 million for national organizations for public education

    [HHS: where does this extra funding come from? The budget table has to show a decrease somewhere for this increase. OMB: do you agree? Is MA spending an appropriate benchmark?]

- **Emphasis on school programs and programs for special populations:** [WORKING GROUP ISSUE] Across all of the cessation and educational efforts, an emphasis on the needs of special populations, such as racial and ethnic minorities and low-income people, should be maintained. For example, the increase in the recommended funding for the media campaign is intended to assure that diverse populations are reached by that effort. Similarly, an emphasis on school programs is important. School programs are accessible to children and effective. Such programs could be funded from the tobacco cessation fund or as a separate spending line. The Settlement does not explicitly fund school programs. DHHS recommends that funding across Settlement funds add up to $180 million, composed of:

    - $25 million for state health education and health agencies
    - $5 million for national education organizations
    - $150 million for local education agencies

- **Structure of tobacco use cessation trust fund:** [WORKING GROUP ISSUE] The Settlement contains little guidance on the uses of this trust fund. DHHS has proposed three ways that its funds could be spent: (1) pay for cessation interventions for all interested smokers; (2) pay for cessation services in Medicare, Medicaid and public health and impose a mandate that private insurance covers smoking cessation; or (3) fund technical assistance and information dissemination as well as public program cessation coverage. The advantage of the first option is that it is consistent with the research trust fund and appears to be the intent of the Settlement; however, its funding may be spent in large part on people who already have private coverage. The second option — that includes a health insurance mandate — comes from the Koop/Kessler report and may better target public funds but is probably politically infeasible. The third option focuses on coordination of activities and making cessation services a regular part of clinical services; its main drawback is that extra funding will be needed. [recommendation?]

CESSATION / EDUCATION FUNDING
(Dollars in Millions; Settlement Amounts Not Inflation of Volume Adjusted)

Budget Line	Year One			Five-Year Total		25-Year Total	
	Baseline	Settlement	DHHS	Settlement	DHHS	Settlement	DHHS
HHS Reduce Use*	na	125	230	825	1,150	5,325	5,750
State Programs/ASSIST	125	75	465	500	2,650	3,000	11,625
Education/Media	46**	500	600	2,500	3,000	12,500	15,000
Cessation Fund	na	1,000	1,000	5,500	5,500	35,500	35,500
TOTAL		1,700	***	9,325	***	56,325	***

* Includes Secretarial initiative on tobacco reduction and school programs

** OMB estimates of current spending on prevention

*** DHHS recommendations are not meant to sum to total but represent options for reallocation of the total amount

C. MISCELLANEOUS

The Settlement funds are not solely dedicated to health and public health investments. Other types spending include: (1) up-front payments, whose use is unspecified; (2) FDA enforcement costs; (3) the "teams' fund"; and (4) civil liabilities fund. In addition, the overall amount of funds available for health investments is reduced by the Settlement's "volume adjuster", the Balanced Budget Act provision reducing the Settlement by its tobacco tax revenue, and possible budget offsets. Although FDA enforcement costs are unlikely to change, the up-front payments, teams fund and civil liabilities fund may all have excess funds that could be used for health investments. Similarly, the offsets to the overall spending could be modified to increase the funding available for health priorities.

- **Up-front payments:** On the date that the statute containing the final terms of the Settlement is signed, the tobacco industry would have to pay $10 billion. The Settlement is silent on the uses of these funds. It appears that this money is intended for the states. These funds may, in fact, be available to supplement the health investments or research funds if there is a deficiency.

- **FDA costs:** The FDA enforcement amount is being reviewed for its sufficiency given the large new responsibility that the agency bears.

- **Teams' fund:** The teams' fund provides temporary compensation to events, teams or entries in such events who lose sponsorship by the tobacco industry. HHS [?] has suggested that a condition of receiving these funds might be that the team use the space previously occupied by tobacco advertisements for health-oriented advertisements. At the end of 10 years, these funds revert to health investment use, being reallocated to public education, FDA enforcement, and community-based programs.

- **Civil liabilities payments**: Under the Settlement, one-third of the base payments (adjusted for volume, described below) is used to pay civil liabilities. Individuals that successfully sue for damages may receive 80 percent of any awards from this fund. The Economic Group questions the soundness of this structure since the industry's liability is limited and the Federal and state governments, who get any unused funds, have an incentive to discourage individuals from suing.

- **Reductions in total spending amounts:** Three policies and assumptions reduce the amount of funds from the Settlement that may be invested. The first is the "volume adjuster", which reduces industry payments in proportion to the decline in adult sales volume for tobacco. Because research suggests that the Settlement could cause a large reduction in tobacco use, the volume adjuster reduces overall payments by $32 billion over 10 years [old estimate]. Second, a last-minute provision of the Balanced Budget Act. requires that the $50 billion in revenue from the 20-cent tobacco tax — intended primarily to fund the children's health initiative — be deducted from the $368 billion. Third, OMB would probably consider these payments like tax revenue and take the standard 25 percent indirect business tax offset. This would lower available funds by as much as $25 billion over 10 years [old estimate].

D. HEALTH INVESTMENTS

The Settlement suggests that the funds not used for research and education / cessation would be used for general health investments. However, there are no specific recommendations about the amount of funds made available for health investments or how funds should be used. This leaves the Administration and Congress with wide latitude in this area.

Amount of funds available: Unlike all other areas of the Settlement's budget and program recommendations, the amount available for health investments is not specified. Instead, it is, in theory, $368 billion over 25 years minus the research, cessation, and education funds. However, in reality, it is much less than those who worked on the Settlement envisioned. This results because of the offsets, described above. Using pessimistic assumptions, there would be only about than $1 to $2 billion per year available for health investments. [old estimated: OMB]

The amount available for spending within the $368 billion could be increased by addressing the causes of the offsets. For example, the tobacco industry payments could be collected in such a way (e.g., as fines) to avoid its treatment as excise tax revenue. Alternatively, some of the up-front payment could be directed toward specific health investments.

There has also be consideration given to whether the $368 billion in industry payments is sufficient, independent of issues about spending. Treasury, Council of Economic Advisers and OMB analysts have carefully reviewed the Settlement payment structure and size. They suggest that there are inadequacies and, specifically, that the amount of the payments should increase. Their options are described in a separate paper, but include, among others, restoring the revenue from the 20-cent tobacco tax and modifying the volume adjuster so funding increases more constantly over time (e.g., by medical inflation). OMB is working on the budget impacts of these options. **[note: add summary of OMB analysis of Treasury options]**

Clearly, each option will have to be weighed for its ability to be passed by Congress, since increasing the tobacco industry payments may well be difficult to support politically. However, decisions about the size and feasibility of any increase should be considered in tandem with decisions about health investments. If there is an explicit link between the increase in the Settlement payments and specific health investments, such as one or two visible, high-priority items, such increases may be more acceptable.

Types of spending: These undedicated funds could be invested in many types of activities, broadly categorized into four groups:

- **Coverage expansions:** The tobacco settlement may be the last opportunity for a coverage expansion in this term. This type of spending may be justified because tobacco-related health costs have been a barrier to expanding coverage to more Americans. However, such investments will require a steady stream of funding, similar to one of the options being examined, that connects payments to health spending growth.

- **Long-term care:** Many chronic and debilitating illnesses are related to tobacco use. Long-term care investments would help people who have suffered as a result.

- **Public health investments**: Many of the best interventions to help people with tobacco-related illness are based in public health. For example, cardiovascular disease programs and immunization initiatives could yield significant improvements in general health.

- **Research:** The $25 billion research trust fund could be supplemented with a special pool for cancer-related or other biomedical research. This may be justifiable since research hold the keys to understanding addiction to tobacco and cures for tobacco-related illness.

- **Congressional and other non-health investments:** It might make sense to set aside a certain dollar amount or proportion of the Settlement for Congressional priorities. This would enable Congress to become more invested in the Settlement because they would be able to develop health initiatives that they could call their own. This poses the risk, however, that funds may be directed to options that are counter to our policy goals. There may also be a need to fund an assistance program for tobacco farmers and other displaced workers by the effects of the Settlement.

Finally, it is critical to point out that only a few of the options described below can be funded from this Settlement — even if its size is increased. Choosing from among the options will depend on answers to such questions as:

- How "tobacco related" should the investment be? Is the link defensible publicly?

- Should there be one large investment (e.g., a coverage expansion) or many small investments (e.g., a series of public health initiatives)?

- To avoid supplanting existing funds, should the investment create a new program? Or, to be efficient, should it expand a program that works but is underfunded?

The following list is comprised primarily of suggestions from DHHS. NOTE: ALL OF THE COST ESTIMATES ARE HHS (SOME WH); NONE HAVE BEEN REVIEWED BY OMB.

COVERING UNINSURED AMERICANS

1. **Medicare buy-in for early retirees:** One of the most troubling insurance trends is the loss of employer coverage for people 55 to 65 years old. This group has, on average, high health costs which pose barriers to purchasing private coverage. This policy allows people age 55/60 to 65 year olds to buy into Medicare with partial premium assistance. If successful, this option could also be linked to a possible increase in the age eligibility for Medicare from 65 to 67 years old.

   Costs: About $2 to 4 billion per year

   Concerns: Expensive (could be moderated); has the possibility of increasing the number of early retirees; excessive adverse selection could create additional structural pressures on Medicare.

2. **Premium assistance for families with job changes:** The most common reason why people lose health insurance is job change or loss. Job changes often tighten a family's income, making it more difficult to purchase insurance. Targeting this group is also least likely to buy out private coverage, since they have lost their employer contribution. This policy provides temporary premium assistance through grants to states for families losing insurance due to job transitions.

   Costs: About $2 to 3 billion per year

   Concerns: This proposal was in the original President's budget but did not attract significant political support. Also, states may be reluctant to operate a new program since they are implementing welfare reform and the children's program.

3. **Children's outreach bonus:** Part of the effort to covering up to 5 million uninsured children is a successful Medicaid outreach campaign. This policy gives states an enhanced Federal matching rate for covering an uninsured child already eligible for Medicaid — the same rate it gets for covering an uninsured child through the new children's program.

   Costs: $500 million to $1 billion per year

   Concerns: Rewards states for covering children that they should cover now. Also, more funding for children's health may be suspect given the recent $24 billion investment.

4. **Raising mandatory Medicaid for young children (0-3 years old):** Young children have a broad range of health needs that might be best met through Medicaid. This policy gives 100 percent Federal match for children ages 0-3 to up to 150 to 200 percent of poverty.

   Costs: About $100 to 430 million per year

   Concerns: Creates complicated mix of matching rates for children. Would require significant changes in the new children's health initiative.

5. **Raising mandatory Medicaid for pregnant women & infants:** Health insurance often removes barriers to critically needed prenatal care. This policy provide 100 percent Federal match for pregnant women and infants up to 150 to 200 percent of poverty.

   Costs: About $530 million to $1.7 billion per year

   Concerns: Since over 30 states have expanded to pregnant women, this risks significant substitution of public funds. Medicaid already covers nearly 40 percent of all births.

LONG-TERM CARE

6. **Home and community-based care program:** Alternatives to institutional long-term care may be cost effective and more acceptable to families of people with long-term care needs. This policy provides grants to states to develop innovative programs for people with disabilities and long-term care needs regardless of income (same as proposed in the Health Security Act).

   Costs: About $8 billion per year

   Concerns: Expensive, and advocates may argue that lower funding will be insufficient; may substitute for care already being provided; states may not feel capable of setting up another program given welfare reform and the children's health implementation.

7. **Medicare respite benefit:** A respite benefit for families of qualified Medicare beneficiaries with Alzheimers and other irreversible dementias will give them needed breaks from providing continuous care to their relatives. This is an expansion of the President's FY 1998 proposal, providing families of Medicare beneficiaries with up to 32 to 96 hours of respite care per year.

   Costs: About $360 million to $1.1 billion per year

   Concerns: Congress rejected this proposal because it is expensive may be subject to fraud since it is administered by home health agencies.

8. **New initiatives for children and pregnant women:** As complements to both the children's health initiative and the 0-3 focus, a range of innovative, new programs could be funded, including providing a "health home" for children; outreach for children with special needs; and post-school activities.

   Costs: From $250 million to sum total of $2.75 billion per year

   Concerns: Some of these are expensive; they are largely untested.

9. **Building on existing programs for children and pregnant women:** Experience has shown that several public health programs can make meaningful improvements in the health of young children and pregnant women. Examples include:

   - Early Head Start: Add to the 143 sites for infants, toddlers, & pregnant women;
   - Immunization programs and universal newborn hearing screening;
   - Home visiting program for pregnant women: Recent studies suggest that home visiting may lessen the likelihood of outcomes like child abuse and neglect.

   Also includes other community programs and residential substance abuse treatment.

   Costs: From $50 million to sum total of $1 billion per year

   Concerns: Could supplant existing funds; substance abuse program may be controversial.

10. **Expanding school-based clinics**: Since most children are in schools, school-based clinics help overcome barriers to preventive and timely primary care. This would fund new clinics and supplement existing clinics in all schools to provide education and comprehensive primary care.

    Costs: $1 billion per year

    Concerns: Could substitute for private coverage.

11. **Cardiovascular disease program:** Cardiovascular disease is the leading cause of death in the United States. However, there is currently no nation-wide public health or outreach initiative to educate health care providers, communities, or the public on how to identify those at risk and take precautions against these diseases. This unprecedented program would expand health communication and public health education efforts, including:

- National media outreach campaign;
- National education program (e.g., educating providers to identify and counsel people about know risks such as tobacco use, obesity, lack of exercise);
- Funds for state-based and community-based programs for cardiovascular disease prevention (e.g., grants to community-based coalitions of providers, hospitals, employers and schools to organize prevention efforts);
- Improved research (e.g., the prevention and impact of obesity).

Costs: $100 to 300 million per year

Concerns: Emphasizes only one tobacco-related disease.

12. **Cancer outreach program:** Too often, many cancers go undetected in their earliest and often most treatable stages. This program would build state- and community-based programs to provide free or low-cost screening to help millions more Americans get tested for various types of cancer, including colon cancer, prostate cancer, and breast cancer as well as provide outreach and education on prevention and early detection.

Cost: $75 million per year

Concerns: Emphasizes only one tobacco-related disease. Supplants private spending.

13. **Health programs for Indian tribes:** The Indian Health Service confronts significant health problems — many of which are tobacco related — with limited resources. This would provide additional resources for urban Indian health, injury prevention, oral health, and sanitation facility construction, among others.

Costs: $250 million per year

Concerns: Large increase over existing funds [HHS: what is baseline spending]

RESEARCH

14. **Double tobacco-related research:** The option to invest the $25 billion in research funds from the Settlement is good for the long-run but lessens the amount of funding available immediately. Additional, immediate funding would allow for more biomedical research to improve treatment and find cures for tobacco-related illness.

Costs: $1.3 billion

Concerns: May be too much emphasis on research; marginal value of funds may be low.

15. **Double investment in cancer research:** According to the National Cancer Institute, over 40 percent of Americans will get cancer, and over 20 percent will die from it. This fund would increase the biomedical research budget for cancer-related research, helping to (1) fund more clinical trials to improve treatments, (2) better understand the genetic links of cancer, and (3) improve communication of the latest research on detecting cancer in its earliest, most treatable forms to providers and all Americans.

Cost: $2 to 3 billion per year

Concerns: Emphasizes one tobacco-related disease. Risks supplanting appropriation.

HEALTH INVESTMENT FUNDING
(Dollars in Millions)

Budget Line	Year One		Five-Year Total	25-Year Total
	Baseline	DHHS/Other	DHHS/Other	DHHS/Other
AVAILABLE FUNDS	na	[OMB]	[OMB]	[OMB]
EXPANDING COVERAGE				
Medicare buy-in for early retirees	0	2,000-4,000	11,100-22,100	—
Premium asst for families w/ job changes	0	2,000-3,000	11,100-16,600	—
Children's outreach bonus	0	500-1,000	4,000-6,000	—
Mandatory Medicaid for children 0-3 yrs	[HHS]	*100-430*	569-2,381	—
Medicaid for pregn. women & infants	[HHS]	*530-1,700*	2,900-9,200	—
LONG-TERM CARE				
Home & comm-based care program	[HHS]	8,000	52,500	—
Medicare respite benefit	0	*360-1,100*	2,000-6,000	19,400-58,200
PUBLIC HEALTH INVESTMENTS				
New initiatives for kids & pregn. women	0	250-2,750	*1,300-14,600*	
Building on existing programs for kids & pregnant women	[HHS]	50-1,000	*270-5,300*	—
Expanding school-based clinics	[HHS]	1,000	*5,300*	—
Cardiovascular disease program	[HHS]	100-300	*530-1,600*	—
Cancer outreach program	[HHS]	75	*400*	—
Health programs for Indian tribes	[HHS]	250	3,500	—
RESEARCH				
Double tobacco research	1,300	1,300	6,900	—
Double cancer-related tobacco research	1,000?	2,000-3,000	10,600-16,000	—
OTHER				
Congress set-aside	0	Undecided	Undecided	—
Workers' displacement fund (farmers)	0	[OMB]	[OMB]	—

NOTE: ALL COSTS ESTIMATES ARE HHS (OR WH); NOT OMB REVIEWED

Italicized estimates are extrapolations of HHS estimates assuming: 5% annual growth for coverage programs and 3% annual growth for public health and research spending

Bucket #2

1-2	3	4 →	
75	100	125	ASSIST

Bucket #1

$125M	$225M	
1-3	4 →	

① media based & non media ed prev cessation
② Research

Bucket #3

- Authorize & fund from Industry Payments a $500M annual, national education-oriented counter-advertising & tobacco control campaign seeking to discourage the initiation of tobacco use by children & adolescents and to encourage current tobacco product users to quit use of the products. Board (independent)

- Authorize & fund from IP a nationwide program, administered through State govts & the private sector of smoking cessation. $1B 1-4 $1.5B thereafter adjusted for inflation Bucket #4

Trust Fund

$400M/yr Bucket #5

Education

CA, MA
- what works
- prevention v. cessation
- kids v. adults
- independent board
- ~~beta~~ evidence of effectiveness

Cessation

Are there effective programs.
ACHPR AMA APA

Delivery system

Current anual spending

Insurance MCD MCR

Evaluation, Mechanism ~~of treatment~~

FDA regulation of cessation drugs

- Current spending
  - States
  - national
  - ASSIST

Current
- who pays
- evaluates effectiveness

under settlement

Specific govt recommendations currently on the books?

Universe of "cessation"

Current NIH budget.

What is missing.
Concerns?

What is missing.
Concerns?

June 30, 1997

Gore Warming Up for a Run at the White House

By RICHARD L. BERKE

DES MOINES -- When Sen. Al Gore ran in the Democratic presidential primaries in 1988, he never found his footing in this crucial early battleground. So he dismantled his flagging campaign here and condemned the early caucuses in "the small state of Iowa" as "madness."

But this weekend, Vice President Al Gore left no doubt of his political awakening. "I love Iowa," he assured voters. Recalling "Field of Dreams," Gore told the audience in the rural community of Prairie City, "Is this heaven? To which Kevin Costner replies, 'No, It's Iowa.' "

And to fit in, Gore changed his outfit at least three times in one day -- from standard blue suit and red tie to open casual shirt and khakis and back again -- depending on the audience.

Despite his protestations about it being "way too early," Gore is running for president. And he is running hard. As Gore's 16-vehicle motorcade snaked around this state Saturday, the route looked like a road map of Democratic constituencies vital to combatants in the caucuses here in the year 2000: unions, farmers, environmentalists and Democratic organizers. (He traded his White House-issue limousine for a Chevrolet Suburban sport vehicle.)

This was Gore's first trip to Iowa since last year's election, and his aggressive -- and early -- courtship underscores how, unlike in 1988, the vice president views this state as crucial to his presidential ambitions. Gore's advisers also said they were preparing for a relentless competition with Rep. Dick Gephardt of Missouri, the House minority leader, who is already mobilizing his operation in the state, and who won the caucuses here in 1988. (Gore placed dead last, with less than 1 percent.)

It did not matter that Gore did not overtly announce his run for president: His carefully orchestrated appearances here, replete with American flags and

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]

From: NICOLE LAWRENCE
To: cessmoke1, cessmoke2, kidsmoke, researchsmoke
Date: 7/14/97 2:49pm
Subject: Tobacco Meetings

There will be a meeeting of the tobacco settlement subcommittees tomorrow, July 15, 1997 at 9:00a (research), 10:15 (cessation & Ed) and 11:30a (health investiments) in the HP Conference Room 441/443E of the Humphrey Building.

If you are unable to attend personally you can attend via conference call.
If you have to call from a nongovernment phone call 1-800-545-4387 and give the conference ID number. This is a meet me call and you must call the number given at the scheduled time. Do not call before the schedule time, because you will be told to call back.

9am - 10:00a S/C on Research
Conference ID# M20529
Access # 32321
Conference # 700-991-1610
If you call from a non governement phone call 1-800-545-4387

10:15a - 11:15a S/C on Cessation and Public Education
Conference ID# M18939
Access # 39235
Conference # 700-991-1632

11:30a - 12:30p S/C on Health Investments
Conference ID# M47441
Access # 54257
Conference # 700-991-1236

If you have any questions please call me at 202-690-6052.

CC: rgibson

Research 7-14-97

CDC Proposal on Applied Research

The work described below is principally on applied and population-based research, much of which is consistent with CDC's mission. The large majority of the work would be conducted through grants to universities (e.g., schools of public health and medical schools) and to state and local health departments (to conduct state and community demonstration projects).

Section III.B.
1. Health Services Research: This work will include access to various types of services, patterns of use, reimbursement, delivery of care, patient compliance, implementation in health care systems, recidivism in programs, cost and cost effectiveness studies, and treatment guidelines. Substantial research is needed on ways to promote long-term cessation among teenagers and young adults. Studies of the effectiveness of selected programs (e.g., self-help, cessation clinics, physician interventions) in various subpopulations are needed. For example, more research is needed to test culturally-appropriate programs and materials in various racial and ethnic groups. Additionally, research should be conducted to finds ways to increase the rates of trying to quit and maintaining abstinence among less educated persons and persons with less income.

ANNUAL COST: $100 million

Section III. B.
2. Public Health and Community: This work will include research and evaluation of public and private policy, community and state programs and laws, field programs, the impact of enforcement, and the role of community agencies in affecting advertising policy norms. Current evaluations of ASSIST, IMPACT and SmokeLess States programs need to be significantly expanded to monitor program and policy implementation down to the local level. Testing of innovations involving community-based and school-based programs to complement the national media campaign, urban-rural differences in program implementation and efficacy, and prevention efforts focused on minority and special populations are also needed.

ANNUAL COST: $150 million

Section III.B.
3. Surveillance/Epidemiologic: This work will include population-based studies of patterns and determinants of tobacco use behaviors (including initiation, cessation, nicotine dependence, brand preference, and product selection) and 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.

A core component of a comprehensive tobacco use prevention and control program is a strong surveillance system for monitoring performance and outcomes. Effective programs will use surveillance data to guide program activities, such as strategic planning and materials development. State-based surveillance systems, such as the Behavioral Risk Factor Surveillance

System (BRFSS), the Youth Risk Behavior Survey (YRBS), and the Pregnancy Risk Assessment Monitoring System (PRAMS) will be enhance through add-on questions, modules, and increased sampling to capture local level and special population data. National data sources, such as the National Health Interview Survey (NHIS) and the National Health and Nutrition Examination Survey (NHANES), will also be enhanced as needed. To adequately address tobacco use prevention and control efforts, traditional surveillance needs to be expanded to include program implementation information, local legislation, and environmental indicators, such as public opinion and extent of media campaign reach. Coordinated efforts will maximize the utility of established surveillance systems, such as CDC's BRFSS, YRBS, PRAMS, NHIS, and NHANES in monitoring cost-effectiveness and impacts of programs.

Serial cross-sectional surveys of adolescents and adults (including pregnant women) will be needed to monitor changes over time in tobacco-related knowledge, attitudes, and behaviors. Studies that assess miscalsmisclassificationver time will also be needed. Additionally, longitudinal studies will allow researchers and policy makers to further assess the initiation and cessation processes. These surveys can be conducted at the state and community level, in addition to the national level. Surveillance of the chemical composition of various tobacco products will be required. Expanded national and state-specific surveillance of environmental tobacco smoke exposure among youth and adults is also needed. Additionally, case-control and prospective studies of the relationship between tobacco-use and various diseases must continue.

ANNUAL COST: $150 million

Section III.B.

4. Behavioral:

Studies are needed to better understand the role of social processes and modeling, developmental risk factors (e.g., prenatal and childhood exposures), price factors, health behaviors and attitudes, and behavioral interventions on initiation and quitting behaviors. In addition, studies that link information on personal variables with those from the environment are needed. Information is needed on special populations, especially the major racial/ethnic groups. Studies that clarify the relationship between the use of nicotine-containing tobacco products and the use of other substances (i.e., whether or not the use of various tobacco products causes the use of other substances) are also needed.

ANNUAL COST: $150 million

Research 7-14-97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

July 11, 1997

TO: Harold Varmus, M.D.
Director, NIH

FROM: Director, NCI

SUBJECT: Tobacco-Related Biomedical Research Trust Fund

Goal:

The goal of this research Trust Fund is to provide substantial funding to allow the Nation to make progress towards reducing the burden of tobacco and tobacco-related disease via:

a) Research into the use and direct effects of tobacco and tobacco products

b) Research into reducing the burdens of tobacco-related diseases

Size of the Trust Fund:

In order to make a significant and sustained impact towards reducing the terrible toll exacted by tobacco use and addiction, we need to provide an amount of research funding commensurate with the enormous burden of disease and disability that tobacco causes. If we assume that 20 to 25 percent of the death and disability in this country can be related to tobacco and that our current investment in research aimed at alleviating all disease is approximately $13 billion. We estimate a need of approximately $3 to $3-1/2 billion per year.

Principles:

a) This Trust Fund should provide for a stable source of funding over long periods of time. For that reason, we propose a mechanism whereby the principal of the Trust Fund is able to be invested so that the income on the investment grows in order to provide $3+ billion a year in stable research funding. The stability for the long-term investment that will be required should entail a protection of the principal, once the fund reaches the capacity to sustain a steady state funding level. Details of the rate of growth and disbursal of funds will require further modelling to achieve the funding goals.

b) The Trust Fund should be used to address the full range of tobacco-related and tobacco-related disease research and the research must be of high quality. To optimize the assurance of high quality and so as to not reinvent funding mechanisms, the Trust Fund income should be funneled through the US Government to be further distributed among well established research structures within the government, including NIH, CDC, AHCPR, VA, etc.

c) In order to assure that the funds are used to achieve an agreed upon program of tobacco-related and tobacco-related disease research activities, an independent periodic review and set of programmatic recommendations should be made by a disinterested body of experts convened by a neutral entity such as the National Academy of Sciences. A three-year review would provide an evaluation of the fund activities and recommend how the funds should be distributed across programs, scientific and medical needs and opportunities, as well as across agencies. Such a regular review should assure the public of the proper use of the funds.

d) There should be a separate and distinct accounting of the Trust Fund monies to assure that they represent supplements to the Nation's investment in tobacco-related and tobacco-related disease research activities and that these supplements fulfill the special goals of the Trust Fund.

e) An attempt should be made to formulate a mechanism to protect the appropriation process for PHS research agencies so that Trust Fund monies do not serve to replace appropriations. For example, no agency can receive monies from the fund in any fiscal year, if they do not receive an appropriation for research equal to or greater than the previous year's appropriation.

f) A Presidentially-appointed Board of Trustees would oversee the investment and fund disbursal of the Trust Fund monies and assure that the quality control processes for independent review and program recommendations take place. This Board would be responsible for implementing the recommendations of the outside review panel, and charging that panel(s) with future review requirements.

Richard D. Klausner, M.D.