Q&A on Tobacco Settlement
June 20, 1997

Q. Did the Administration help close the deal?

A. No. My staff monitored the talks closely so that we would be in a position to evaluate and respond to any possible settlement. We consistently told the parties that they would have to close an agreement on their own, and they were able to do so without any help from the Administration.

Q. How will you proceed?

A. I have asked my Domestic Policy Advisor, along with the Secretary of Health and Human Services, to undertake a thorough public health review of this agreement. They will consult with all interested agencies, members of Congress, and the public health community.

Q. How long will the review take?

A. The review will take as long as necessary to conduct a careful analysis, but we will seek to work promptly and expeditiously. We expect this to be a matter of weeks, not months.

Q. Dr. Kessler and Dr. Koop have asked in a letter to you that you give them 30 days to complete their own review before signing off on anything. Are you going to wait?

A. I intend to consider closely the views of the public health community, including Drs. Koop and Kessler, before rendering any judgment on the settlement. But it is premature to commit to any firm timetable for reaching my conclusion.

Q. What will you look at in evaluating this agreement?

A. We will evaluate whether this agreement protects the public health -- and particularly the health of our children. We will pay special attention to the part of the agreement dealing with FDA jurisdiction. The actions the FDA has taken under this Administration forced the industry to the bargaining table, and we will insist that the FDA has all necessary authority to regulate nicotine and tobacco products. We also will carefully review the financial terms of the settlement, including whether the money will go toward protecting the health of our children and the general public.

Q. The final deal limits punitive damages -- a key concession to the tobacco industry. Won't you oppose that given your previous opposition to caps on punitive awards?

A. The limitation on punitive damages for past misconduct is not a deal-breaker for us. We understand that the attorneys general extracted substantial concessions from the tobacco companies for this limitation, and we will evaluate whether the agreement as a whole advances the nation's public health interests.

Q. Are you taking a political risk in considering approval of this settlement?

A. This isn't about politics; it's about protecting the public health. We didn't think about politics when we took on the tobacco companies last year with our announcement of the FDA rule. And we won't look to politics now in evaluating this agreement.

Question and Answer on Tobacco Settlement Proposal Review Process
June 27, 1997

Q: **Can you explain in more detail how the Administration's review is proceeding?**

A: Bruce Reed, the President's Domestic Policy Advisor, and HHS Secretary Shalala, are leading the review. They have established four groups made up of fairly senior White House staff and staff from a number of federal departments including HHS, Justice, Labor, EPA, and Treasury. There is a regulatory group, a program and budget group, a legal group, and an industry performance and accountability group. These groups will subject the proposed agreement to the strictest scrutiny, focusing particularly on its affect on the public health and stopping children from smoking, as the President requested.

Mr. Reed and Secretary Shalala will also be seeking the advice of leaders in the public health community, including the major public health organizations, Drs Koop and Kessler, and the community-level tobacco control advocates.

(more detailed descriptions of groups below)

Q: **Will you be consulting with Congress?**

A: We will also be consulting extensively with Congressional leaders, including the Chairs and Ranking Members of the relevant Committees, and many other members of Congress who care a great deal about tobacco-related matters. The President is obviously aware of the important role Congress will play. To advance the public health, Congress would need to conduct a thorough debate of the issues and translate the agreement into detailed legislation.

Q: **Can you say any more about the President's reaction to the settlement now that he has had a week to study it?**

A: First, he is looking at this in the context of the significant accomplishments his administration has already achieved in the fight to reduce death and illness caused by tobacco. He views the proposed settlement as an opportunity to advance the public health even further. He believes we should make the most of this historic chance to do everything we can to protect our children and our country from the dangers of tobacco. He expects it will take us some time to make a serious, informed judgment on the terms of this settlement, but he is delighted that the actions of his administration and the steadfast efforts of the attorneys general have permanently changed the tobacco landscape.

Q: **Can you tell us whether the President has any comment on the sharp criticisms of the proposal made by Drs. Koop and Kessler and the members of their advisory committee?**

A. The President has said from the very beginning that he intends to consider very closely the views of the public health community, including Drs. Koop and Kessler, before rendering any judgment on the proposed settlement. The President shares some of their questions. As the President noted last weekend, in light of the important role FDA jurisdiction played in advancing this issue, he was concerned by some of the changes in FDA jurisdiction that were contained in the proposed settlement. Drs. Koop and Kessler have voiced their concerns about this and other issues, and we will certainly be looking closely at their committee's report.

Q. President Clinton has said the review will be done in 30 days. Are you going to meet that deadline?

A. We are certainly trying to work within that time frame, but we will be sure to conduct a careful and thorough analysis.

Q. Who will lead the HHS team?

A. Secretary Shalala and Deputy Secretary Kevin Thurm.

Q. Who will lead the DPC team?

A. Bruce Reed, and Deputy Assistants to the President Elena Kagan and Chris Jennings.

Q. Have any of the panels met?

A. All of them have met at least once.

Q. Why will this take so long?

A. This is a critical public health issue and the agreement is complex, so we are going to do an expeditious but careful and thorough review. As the President has said, protecting the public health -- and particularly our children's health -- is our primary concern. We know that nearly 3,000 young people become regular smokers each day, and nearly 1,000 of these children and adolescents will die early from their use of tobacco products. We must ensure the agreement is in the best interest of public health and children's health.

Q. **How many agencies are involved in the review?**

A. 12 agencies (HHS, DOJ, Treasury, EPA, Interior, VA, DOD, USDA, DOL, GSA, State, and USTR), and 8 White House offices (DPC, NEC, CEA, OVP, Leg Affairs, Counsel, OMB, and OSTP)

Q. **How many people are involved?**

A. TBD

Q. **Can you explain what each of the four groups will cover and which agencies will participate?**

A. The Regulatory Issues group, convened by Elena Kagan, will look at FDA regulation of product content, access, advertising, and labeling, and proposed restrictions on environmental tobacco smoke in public buildings and workplace settings. Participating White House offices are DPC, OMB, OVP, NEC, and OSTP. Participating agencies are HHS, DOJ, DOL, GSA, EPA, and Treasury.

The Program and Budget Issues group, convened by Chris Jennings, will examine proposed uses of settlement funds, including spending on programs to reduce smoking and expand children's health care coverage, smoking cessation programs, and investments in health research, including nicotine research. Participating White House offices are DPC, OMB, NEC, OVP, and OSTP. Participating agencies are HHS, Treasury, DOL, USDA, Interior, VA, and DOD.

The legal Issues group, convened by Elena Kagan, will examine, among other things, issues around liability, enforcement, compliance, and the disposition of industry documents. Participating White House offices are DPC, OVP, NEC, and Counsel. Participating agencies are DOJ, HHS, Treasury, EPA, and Interior.

The Industry group, convened by Bruce Reed, will analyze the economic effects of a settlement, examine the proposed smoking reduction targets, penalties, and incentives, and evaluate the potential international impacts of the settlement. White House offices are DPC, NEC, CEA, OVP, OMB, and OSTP; participating agencies are: HHS, Treasury, DOL, USDA, USTR, State, and DOD.

--- DRAFT --- 6/24 **Tobacco Working Groups**

I. **Regulatory Issues** (Chair -- Elena Kagan) White House (DPC, OMB, OVP, NEC, OSTP) Agencies (HHS, DOJ, DOL, GSA, EPA, Treasury)

A. FDA regulation of product, access, advertising and labeling

B. Environmental tobacco smoke

II. **Program and Budget Issues** (Chair -- Chris Jennings) White House (DPC, OMB, NEC, OVP, OSTP); Agencies (HHS, Treasury, Labor USDA)

A. Children's Health Care

B. Education (including grass roots programs)

C. Smoking Cessation

D. Nicotine Research

III. **Legal Issues** (Chair -- Elena Kagan) White House (DPC, OVP, NEC); Agencies (DOJ, HHS, Treasury)

IV. **Industry Performance and Accountability** (Chair -- Bruce Reed) White House (DPC, NEC, CEA, OVP, OMB, OSTP) Agencies (HHS, Treasury, DOL, USDA, USTR, State)

A. Economic analysis

B. Targets, penalties, incentives

C. International

TOBACCO SETTLEMENT ISSUES FOR DISCUSSION
8/4/97

I. FDA Jurisdiction

Strengths -- codifies FDA authority; sets explicit risk reduction standard for tobacco products.
Weaknesses--FDA must make new findings, overcome new procedural hurdles, meet new standard of proof, is given reduced deference, and can't act within certain time frames.
Possible Objectives-- No change to FDCA; set risk reduction standard (modified); require more than notice and comment rulemaking

A. New Findings

1) To reduce or eliminate nicotine, FDA must find that product modification will:
   a) result in significant reduction in health risk;
   *modify to address risk to entire public, not just smokers
   *drop "significant" and/or drop as finding
   b) be technologically feasible;
   *drop as finding, leave as factor FDA must consider
   c) not create a black market.
   *drop as finding, leave as factor FDA must consider.
2) To eliminate nicotine or take "equivalent" action, FDA must consider number of dependent users, availability and demonstrated market acceptance of alternate products.
*drop or modify

B. Time Restrictions

1) FDA can make no changes to access provisions for 5 years.
2) FDA must wait 12 years, and phase in over at least two years.
*drop or modify (1) and/or (2)

C. New Procedural Hurdles

1) Formal rulemaking required to reduce nicotine
2) Formal rulemaking or Part 12 hearing (at industry's option) to eliminate nicotine or take equivalent action.
*Maintain FDCA procedures, require formal rulemaking, or adopt intermediate procedure

D. New Standard of Evidence / Reduced Deference--

1)"substantial evidence" for reducing nicotine;
2) "preponderance of evidence" for eliminating nicotine or equivalent action:
3) deference in judicial review depends on "Agency expertise."
*delete deference provision
*drop standards

II. Look Back Provisions

Strengths -- embraces Administration's youth reduction goals
Limitations --Maximum impact estimated at 8 cents per pack; 2 cents after 75% abatement for companies making "good faith" effort to comply; penalty is lowered if sales decline; applying penalty industry wide reduces each company's incentive to meet targets ("free-rider" problem)
Objective -- provide meaningful incentive for companies to meet targets.

A. Level of Penalty

*Make penalty substantially higher than foregone profits (e.g. 3x profits)
*Make non-linear (pay higher penalties further from the target)
*Remove annual $2 billion cap
*Remove tax deductibility (reiterate these payments are fines)
*Remove volume adjustment
*Eliminate double counting provision
*Consider non-economic incentives, e.g. raising age to 21

B. Free Rider Problem

*Assess penalties firm-by-firm
- collect data (e.g. expand Michigan survey to collect brand information)
- use base number of teens that smoked each firm's product

C. Abatement for "Good Faith"

* Make only limited part of penalty eligible for abatement for good faith or drop

III. Document Disclosure

Strengths-- establishes a national tobacco document depository of existing documents discussing health research/marketing to youth (a 3-judge panel reviews trade secret and privilege claims); any member of the public can challenge claim; authorizes in camera review of privileged documents by 3-judge panel without prima facie showing of evidence of crime or fraud

Limitations -- decisions binding on [federal and] state courts; binds all future litigants not party to the settlement; panel does not have same incentive as trial judges to resolve privilege disputes in a timely matter, leading to delay; industry can still assert full privilege claim

Possible Objectives -- Centralize documents but preserve and enhance plaintiffs's discovery in litigation

A. Preemption of current/future litigants

*create national depository but one in which panel decisions do not bind (state?) litigants;

B. Ease discovery in litigation

* eliminate procedural hurdle of prima facie showing prior to in camera review (apply document depository provision)

*alter substantively the requirements industry must meet to sustain a privilege claim for certain types of documents (e.g. health research) in court or in national depository

IV. FUNDING

Strengths -- Substantial sum

Limitations -- Net estimated to be less than half of gross revenues; minimally negative to positive effect on shareholders, profits.

Possible Objectives --

A. Level of Funding -- How much pain is enough for liability protections, antitrust ~~predictions?~~ protections?

1) Annual payment functions like an excise tax estimated at about 60 cents and is expected to reduce smoking among adults by 15% and among teens by 22%

2) Payment expected to reduce profits by at most 10% and could lead to a rise in stocks and profits.

3) Actual federal and state revenues expected to be less than half of gross payments due to offsetting effects (e.g. decreased excise tax; CPI adjustment; indirect business tax offset) .

*increase the annual payment amount (raises price of cigarettes)

*increase the initial payment (borne by shareholders)

*increase excess profits tax

*replace industry payments with Federal excise tax ($1 raises about $15 billion/yr)

B. How funds are spent —TBD

1) Trust fund -- tobacco-related research
2) Earmarked smoking cessation and education
3) Health care investments (size?)

V. Immunity from Class Actions and Punitive Damage Awards

Strengths -- Industry incentive to settle.
Weaknesses -- Arguably removes only real fiscal deterrent to harmful behavior
Objectives -- ?

A. Constraints on class actions.

*drop prohibition but let fall under cap
*remove prohibition on joining, consolidating, aggregating individual suits

B. Disincentives for future misconduct

*No prohibition on punitives for future misconduct; cap does not apply

VI. Farmers

Strengths -- N/A
Weaknesses -- excludes farmers
Objectives -- include in settlement; consider Democratic members' proposal, possibly 2% of settlement funds dedicated to assistance.

VII. Environmental Tobacco Smoke (ETS)

Strengths--More certain and in some ways stronger than OSHA standard (e.g. covers some businesses with fewer than 10 employees; does not preempt state and local coverage)
Weaknesses -- Broad exemption for hospitality industry leaving those workers at greatest risk unprotected and may preempt OSHA's ability to act in hospitality industry.
Objectives -- support provision and(?) seek to narrow exemption.

Additional Issues

- Advertising/protocol
- Other claimants (asbestos, pension plans/unions, VA, RECA fund)
- International
- Bankruptcy
- Reduced risk products
- Licensing
- Other regulate tobacco (smokeless, Liggett)
- Cigars
- Licensing/compliance/minors
- minorities
- fire-safe cigarette

TOBACCO SETTLEMENT ISSUES FOR DISCUSSION
8/4/97
(*) = possible approaches to addressing concerns, not in any particular order

I. FDA Jurisdiction

Strengths -- codifies FDA authority; sets explicit risk reduction standard for tobacco products.
Weaknesses--FDA must make new findings, overcome new procedural hurdles, meet new standard of proof, is given reduced deference, and can't act within certain time frames.
Possible Objectives-- No change to FDCA; or set risk reduction standard (modified); and/or require more than notice and comment rulemaking

A. New Findings

1) To reduce or eliminate nicotine, FDA must find that product modification will:
   a) result in significant reduction in health risk;
   *modify to address risk to entire public, not just smokers
   *drop "significant" and/or drop as finding
   b) be technologically feasible;
   *drop as finding, leave as factor FDA must consider
   c) not create a black market.
   *drop as finding, leave as factor FDA must consider.
2) To eliminate nicotine or take "equivalent" action, FDA must consider number of dependent users, availability and demonstrated market acceptance of alternate products.
*drop or modify

B. Time Restrictions

1) FDA can make no changes to access and volumes provisions for 5 years.
2) FDA must wait 12 years, and phase in over at least two years.
*drop or modify (1) and/or (2)

C. New Procedural Hurdles

1) Formal rulemaking required to reduce nicotine
2) Formal rulemaking or Part 12 hearing (at industry's option) to eliminate nicotine or take equivalent action.
*Maintain FDCA procedures, require formal rulemaking, or adopt intermediate procedure

D. New Standard of Evidence / Reduced Deference--

1)"substantial evidence" for reducing nicotine;
2) "preponderance of evidence" for eliminating nicotine or equivalent action:
3) deference in judicial review depends on "Agency expertise."
*delete deference provision

*drop standards

II. Look Back Provisions

Strengths -- embraces Administration's youth reduction goals
Limitations --Maximum impact estimated at 8 cents per pack; 2 cents after 75% abatement for companies making "good faith" effort to comply; penalty is lowered if sales decline; applying penalty industry wide reduces each company's incentive to meet targets ("free-rider" problem)
Objective -- provide meaningful incentive for companies to meet targets.

A. Level of Penalty

*Make penalty substantially higher than foregone profits (e.g. 3x profits)
*Make non-linear (pay higher penalties further from the target)
*Remove annual $2 billion cap
*Remove tax deductibility (reiterate these payments are fines)
*Remove volume adjustment
*Eliminate double counting provision
*Consider non-economic incentives, e.g. raising age to 21

B. Free Rider Problem

*Assess penalties firm-by-firm
- collect data (e.g. expand Michigan survey to collect brand information)
- use base number of teens that smoked each firm's product

C. Abatement for "Good Faith"

* Make only limited part of penalty eligible for abatement for good faith or drop

III. Document Disclosure

Strengths-- establishes a national tobacco document depository of existing documents discussing health research/marketing to youth (a 3-judge panel reviews trade secret and privilege claims); any member of the public can challenge claim; authorizes in camera review of privileged documents by 3-judge panel without prima facie showing of evidence of crime or fraud
Limitations -- decisions binding on [federal and] state courts; binds all future litigants not party to the settlement; panel does not have same incentive as trial judges to resolve privilege disputes in a timely matter, leading to delay; industry can still assert full privilege claim
Possible Objectives -- Centralize documents but preserve and enhance plaintiffs's discovery in litigation

A. **Preemption of current/future litigants**
*create national depository but one in which panel decisions do not bind (state?) litigants;

B. **Ease discovery in litigation**
* eliminate procedural hurdle of prima facie showing prior to in camera review (apply document depository provision)
*alter substantively the requirements industry must meet to sustain a privilege claim for certain types of documents (e.g. health research) in court or in national depository

IV. FUNDING

Strengths -- Substantial sum
Limitations -- Net estimated to be less than half of gross revenues; minimally negative to positive effect on shareholders, profits.
Possible Objectives --

A. **Level of Funding** -- How much pain is enough for liability protections, antitrust protections?
1) Annual payment functions like an excise tax estimated at about 60 cents and is expected to reduce smoking among adults by 15% and among teens by 22%
2) Payment expected to reduce profits by at most 10% and could lead to a rise in stocks and profits.
3) Actual federal and state revenues expected to be less than half of gross payments due to offsetting effects (e.g. decreased excise tax; CPI adjustment; indirect business tax offset) .
*increase the annual payment amount (raises price of cigarettes)
*increase the initial payment (borne by shareholders)
*increase excess profits tax
*replace industry payments with Federal excise tax ($1 raises about $15 billion/yr)

B. How funds are spent -- TBD

1) Trust fund -- tobacco-related research
2) Earmarked smoking cessation and education
3) Health care investments (size?)

V. Immunity from Class Actions and Punitive Damage Awards

Strengths -- Industry incentive to settle.
Weaknesses -- Arguably removes only real fiscal deterrent to harmful behavior
Objectives -- ?

A. Constraints on class actions.

*drop prohibition but let fall under cap
*remove prohibition on joining, consolidating, aggregating individual suits

B. Disincentives for future misconduct

*No prohibition on punitives for future misconduct; cap does not apply

VI. Farmers

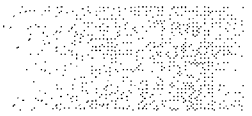
Strengths -- N/A
Weaknesses -- excludes farmers
Objectives -- include in settlement; consider Democratic members' proposal, possibly 2% of settlement funds dedicated to assistance.

VII. Environmental Tobacco Smoke (ETS)

Strengths--More certain and in some ways stronger than OSHA standard (e.g. covers some businesses with fewer than 10 employees; does not preempt state and local coverage)
Weaknesses -- Broad exemption for hospitality industry leaving those workers at greatest risk unprotected and may preempt OSHA's ability to act in hospitality industry.
Objectives -- support provision and(?) seek to narrow exemption.

Additional Issues

- Advertising/protocol
- Other claimants (asbestos, pension plans/unions, VA, RECA fund)
- International
- Bankruptcy
- Reduced risk products
- Licensing
- Other regulate tobacco (smokeless, Liggett)
- Cigars
- Licensing/compliance/minors
- Minorities
- Preemption
- Fire-safe cigarettes



Jerold R. Mande

07/09/97 07:50:41 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP
cc: Elena Kagan/OPD/EOP, Elizabeth Drye/OPD/EOP
bcc:
Subject: Re: Notebook

Issue 1 -- Reduced risk cigarettes. First, what is a "reduced risk cigarette?" Today the market includes ultra-light (1-6mg tar), light (6-15mg tar), and full-flavor (>15mg tar). These are industry defined categories. Most experts are not sure whether any of these actually reduce risk. We do know, for example, that since light products have come to dominate the market (since the early '80s) the amount of smoking-related illness has increased. There are at least a couple of reasons for this: the industry has done a good job marketing light cigarettes as more healthful alternatives so smokers who might have otherwise smoked less or quit switch to light cigarettes instead (according to CDC about 1/3 to 1/2 of smokers switch to light or ultra-light brands because they believe they are less hazardous); and smokers simply smoke light cigarettes more forcibly or more often.

There have been cigarettes that might actually reduce risk, although the studies have been industry studies. There was PM's Next (no nicotine) and RJR's Premier and now Eclipse (which is currently being test marketed)(these heat rather than burn and deliver nicotine with little or no smoke, but are high in carbon monoxide). There is also a nitrosamine-free cigarette under development that if feasible would reduce risk. I don't know much about palladium, it may have tried to reduce risk through added chemicals, and I don't know what happened to it. So far as I know no company has successfully mass marketed a true reduced-risk cigarette. Many nicotine/tobacco experts will insist there are no safer cigarettes (inhaling smoke will always result in significant health risks) only safer forms of nicotine delivery (patches, gums, inhalers, nasal sprays).

Issue 2 -- Developing less hazardous cigarettes. As you know for liability reasons, companies have not pursued mass marketing of a reduced risk cigarette although they have invested heavily in designing and studying a possibly safer product. The settlement does provide a number of mechanisms designed to encourage less hazardous cigarettes. It is not yet clear to me whether these provisions, which layout a framework for FDA oversight of products and claims, conditions for advertising, and disclosure of industry research will help produce a public health gain, but it is worth pursuing.

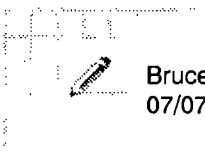
Issue 3 -- Who smokes low-yield cigarettes? Three national surveys, conducted in 1986, 1987, 1993, shed light on low-yield cigarette smokers. Female smokers were more likely (84% to 63%) to smoke light or ultra-light cigarettes. Among 10 - 18 years-old, females were out in front 53% to 27%. As for race, in 1987, whites were more likely (77%) than Hispanics (68%) or African-Americans (52%). Among youth: whites (53%), Hispanics (44%), African-Americans (15%). Education is also a factor -- as education increases so does use of low-yield products. This is true for both adults and kids. Kids who do better in school are more likely to smoke low-yield cigarettes.

Issue 4 -- African-American smoking rates. One real public health victory has been the decline in smoking among African-Americans. Following a trend which began in the late '70s, while smoking among youth was rising to around 30%, smoking among African-Americans was plunging to single digits.

Unfortunately, in the last couple of years, smoking among African-Americans has begun to increase. We do know that the difference is real. CDC studies have ruled out confounding factors such as African-Americans are using other drugs instead or African-American smokers are dropping out of school.

What the expert don't know is why. Theories include (ranging from where there is some data to urban myth): African-American girls don't accept the thin body image popular with white girls; African-American parents are more actively involved, particularly on smoking; African-American youth don't need to seek more risk in their lives; the K in Kool (once the most popular cigarette among blacks) is for the KKK.

Bruce N. Reed



Bruce N. Reed
07/07/97 08:13:28 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP, Jerold R. Mande/OSTP/EOP

cc: Elena Kagan/OPD/EOP
Subject: Notebook

Thank you so much for the notebook you put together last week. It made excellent airplane reading. At some point, I would also like to read the rule in its entirety, unless you want to talk me out of it.

A couple random questions occurred to me while going through your material. They're probably not that relevant, but I thought you might have answers off the top of your head:

1. Whatever happened to the Liggett palladium cigarette? Would a company be as reluctant now to come forward with a reduced risk cigarette? Do the provisions in the settlement help?

2. What kind of people smoke low-yield cigarettes? Are they demographically different from smokers as a whole?

3. Do we know why African-American youth smoke less than white and Hispanic youth? Is that the case with marijuana as well? This seems particularly striking if as the Surgeon General's report says, there is a close correlation between smoking and socioeconomic status, single-parent households, and other burdens that African-American young people are more likely to encounter.

I also am enthralled with the Kluger book. I'm only up to the 1950s, but I'm already convinced that there wouldn't be a tobacco industry without advertising (and nicotine, of course). Elena had the inspired idea that we should bring Kluger in here to talk with us. Maybe we could do that early next week (almost enough time to finish the book).

CLINTON ADMINISTRATION OUTLINES TOBACCO SETTLEMENT REVIEW PROCESS

Today, during the signing of the Safe and Drug-Free Communities Act, President Clinton reiterated his commitment to a rigorous public health review of the proposed settlement. The President also announced that Secretary of Health and Human Services Donna E. Shalala and Domestic Policy Advisor Bruce Reed will lead the comprehensive analysis.

Public Health Review

As President Clinton said today, the Administration's preliminary analysis will be conducted by four interdepartmental review panels. Each panel will include representatives from the Domestic Policy Council (DPC) and the Department of Health and Human Services (HHS), and, where appropriate, all of them will also include representatives of other federal agencies, such as the Departments of Treasury, Justice, Labor, Agriculture, Veterans' Affairs, Interior, and Defense, the General Services Administration, and the Environmental Protection Agency. The four panels will focus on four key areas:

- **Regulatory Issues.** The regulatory panel will primarily review the elements in the proposed settlement affecting FDA jurisdiction. The panel will also examine issues surrounding environmental tobacco smoke.

- **Program and Budget Issues.** The program and budget panel will look at proposed uses of settlement funds, including the anti-smoking advertising campaign, grassroots programs, smoking cessation, and any issues that involve research on nicotine, tobacco and health, and smoking cessation.

- **Legal Issues.** The legal panel will examine issues around liability, enforcement, compliance, and the disposition of tobacco industry documents.

- **Industry Issues.** The industry issues panel will examine the settlement's proposed targets, penalties and incentives; evaluate potential international impacts of the settlement; and conduct an economic analysis.

President Clinton's Plan to Reduce Youth Tobacco Use

On August 23, 1996, President Clinton announced the nation's first-ever comprehensive program to protect children from the dangers of tobacco and a lifetime of nicotine addiction. The President's program was launched with the publication of the Food and Drug Administration's (FDA) final rule on tobacco and children, and with FDA's initiation of a process to require tobacco companies to educate children and adolescents -- using a national multi-media campaign -- about the dangers of cigarettes and smokeless tobacco. The first provisions of the rule -- making 18 the age for the purchase of tobacco products nationwide and requiring photo IDs for anyone under age 27 -- became effective February 28, 1997. The President's comprehensive and coordinated plan is intended to reduce tobacco use by children and adolescents by 50 percent in seven years. This ambitious initiative will work to accomplish this objective while preserving the availability of tobacco products for adults. The proposed tobacco settlement will be evaluated within this framework to evaluate whether it meets the President's objectives.

Working Toward Our Fundamental Goal

As the President has said, protecting the public health -- and particularly our children's health -- is and has always been our primary concern. We know that nearly 3,000 young people become regular smokers each day, and nearly 1,000 of these children and adolescents will die early from their use of tobacco products. We must do everything in our power to dramatically reduce smoking by young people because they deserve a life free from the disease that comes with using tobacco.

DRAFT

1. FDA JURISDICTION

The proposed settlement assures jurisdiction over cigarettes and spit tobacco products, and places that authority with FDA. The settlement raises a number of issues about the scope of FDA's authority, including FDA's ability to regulate the nicotine content of these products.

The precise scope of FDA's authority beyond cigarettes and spit tobacco is not clear in the settlement. The word "etc." is actually used on page 13 of the settlement document to describe FDA's jurisdiction over tobacco products. What remains unclear is whether the agency remains free to investigate cigars and other tobacco products, and then assert jurisdiction and apply the final rule to cigars and these other products. (One of the negotiators of the settlement has stated that FDA would be permitted under the deal to investigate, assert jurisdiction, and apply the final rule to cigars and other tobacco products to the extent it is permitted to do so under current law.)

The settlement considerably alters FDA's authority over nicotine. New substantive and procedural obstacles would be placed in the agency's way before nicotine levels could be reduced or eliminated. The substantive hurdles include having to demonstrate: (1) a significant reduction in risk; (2) technological feasibility; and (3) that a significant demand for contraband will not be created. The contraband criterion has been heavily criticized by the President and many in the public health community. In addition, the safety standard apparently allows FDA only to consider the health risks to current smokers, which would prevent consideration of risks to future smokers and those affected by second-hand smoke. Furthermore, the agency would have to wait 12 years before it could eliminate nicotine. The new procedural burdens on the agency include having to employ "formal" rule making which is much more cumbersome and time-consuming than "informal" rule making procedures ordinarily used by FDA. The combined effect of the new substantive and procedural criteria would probably result in the agency receiving far less deference by a reviewing court if FDA's actions were challenged.

Of the new substantive criteria, the one that seems in principle to make sense is the safety standard. This provision is based on the concept of "risk reduction," rather than the current statute's notion of demonstrating safety and efficacy. It would probably need to be re-drafted to overcome the problems described above. Nevertheless, a "risk reduction" approach for products as dangerous and addictive as cigarettes and spit tobacco may provide FDA with more flexibility to address the problems associated with tobacco use.

Overall, however, current law enables FDA to address the nicotine issue unencumbered by the numerous substantive and procedural criteria included in the settlement. In any resulting court challenges under current law FDA would receive a fair degree of deference by reviewing courts. The new provisions in the settlement might effectively prevent or seriously delay a future FDA from reducing the nicotine content of tobacco products.

Options for consideration include: (1) codifying the agency's existing authority over tobacco products, as affirmed by the federal district court; and/or (2) converting the mandatory criteria in the settlement into mere "considerations" that FDA, in its discretion, could decide to evaluate in any agency action.

2. DISCLOSURE OF TOBACCO INDUSTRY DOCUMENTS

The settlement provides for the public disclosure of tobacco industry documents in a national tobacco industry document depository. The settlement further provides a mechanism by which there will be binding judicial determinations by a three-judge court regarding the disclosure of documents that the industry currently claims are protected as trade secrets or are protected by the attorney-client or attorney-work product privilege.

We have been told that the settlement is not intended to affect FDA's existing authority to request and inspect certain documents for regulatory purposes. However, the settlement's mechanism for reviewing privileged documents is extremely cumbersome and time-consuming, and it appears to be the mechanism that FDA would be subject to along with States, public and private litigants, other health officials, and the public. If the agency is required to follow the settlement's time-consuming procedures, it would make obtaining documents the agency has a legal right to in a timely fashion very difficult and could seriously hamper FDA's ability to meaningfully regulate tobacco products. This raises the question of whether there should be additional authority for FDA in this area. If there were to be an expansion of the settlement's terms, it would be important to seek subpoena authority for FDA, perhaps the only federal agency with major regulatory responsibility that does not currently have compulsory process.

The tobacco industry has historically gone to great lengths to protect the confidentiality of its documents, thereby concealing its actions and virtually all of its scientific information about its products, including their addictiveness. This secrecy has served the industry well and the protection of confidential documents is extremely important to the industry in this settlement. Because of the industry's history of secrecy, the issue of document disclosure has been debated publicly, and there are those who are emphatic that there should be no settlement until after all of the industry's documents have been disclosed and there is a more complete understanding of the true extent and nature of the industry's actions and scientific knowledge. Public health advocates argue that only when all the industry's information is public can the terms of the settlement be accurately evaluated and an informed decision be made whether to accept it.

In addition, if this settlement is adopted, the cases brought by the States will end, and the States will have to obtain documents by means of the settlement's mechanism. This is potentially very important because it would block the efforts of the State of Minnesota, which is in the process of piercing the industry's claims of privilege for its documents.

Finally, the Department of Justice questions the use of a threee-judge panel to make disclosure determinations on both constitutional and policy grounds. In addition, serious reservations have been expressed about the fairness and appropriateness of a one-time nationally-binding determination of the public disclosability of these important documents.

3. REDUCED RISK PRODUCTS

The settlement contains provisions regarding the review and approval of "reduced risk" tobacco products. Under these provisions manufacturers would be allowed to make health claims if there were scientifically-based evidence that the product "significantly reduces the risk to health" from ordinary tobacco products. FDA is authorized to exempt such products from the advertising restrictions that apply to other tobacco products. There are also provisions that are designed to provide incentives to manufacturers to make reduced risk technology widely available, and FDA can require the introduction of such technology into the market after formal rulemaking. There are also provisions that give FDA authority to review the non-tobacco ingredients of cigarettes and prohibit its use unless the manufacturer can demonstrate that the ingredient is not harmful under the intended conditions of use. Manufacturers would also be required to disclose ingredients of tobacco products following rules similar to those used by food manufacturers.

Several serious issues are raised by the reduced risk provisions. First, the settlement appears to assume that reduced risk tobacco products can be developed and that these products should be marketed in the U.S. The public health community is split on this issue, and there are very strong opinions on both sides of the argument. This is a very complex question that should be the subject of vigorous national debate before being decided. That debate has not taken place, and it would be unwise and premature to settle such a momentous question in the settlement at this time. It would be more appropriate for the agency to decide that question in the future.

Second, while the settlement allows FDA to approve health claims for reduced risk products, it is counterintuitive to allow health claims for a product that is so inherently dangerous. It is hard to imagine what health claims could be scientifically substantiated and therefore approvable by the agency. There would be concern that these claims would be perceived by the public as meaning that the products are safe, as opposed to only marginally less dangerous. This perception could have the effect of deterring smokers from quitting or encouraging individuals to start. (There is a separate and more detailed discussion of health claims elsewhere.)

Third, FDA is concerned with the standard that the settlement imposes for determining whether a tobacco product poses less of a health risk. Instead of a scientific standard such as "reasonable assurance of safety and effectiveness" or "deleterious to health" which the agency currently uses, the settlement would have the agency determine what an "objective, reasonable consumer would believe pose[s] less of a health risk." This is a much weaker and difficult to define standard that would provide little public health protection.

Fourth, it appears that reduced risk products would also be subject to mandatory categorization as Class II products. This is troubling because it limits the agency's authority over such products before we even know what they are. It is inappropriate and premature to predetermine the class of these products before they have been developed and to remove the agency's ability to determine how best to regulate such products based on their own safety and other characteristics. The agency strongly believes that it should retain its full current authority, and the flexibility that it provides, to determine how best to regulate each product.

Fifth, the settlement provisions under which the agency would require the introduction of reduced risk products are also troublesome because they are very vague. They impose a very daunting procedural requirement (formal rulemaking) that the agency must meet in order to take action. It is also not clear how the agency would determine that reduced risk products are technologically feasible.

Finally, there are several difficulties with the provisions regarding ingredient disclosure. The standard that is imposed for ingredient disclosure is the weaker food labeling requirement rather than the more stringent disclosure authority that is currently provided for devices. Under the food labeling rules, for example, many harmful ingredients could be hidden by using bland terms such as "flavoring." Further, the industry is given 5 years to provide available safety data regarding each ingredient (query whether the agency has the ability to require a manufacturer to develop data if none exist), while FDA is given 90 days to review all safety data. This is not only an inadequate amount of time for the agency to act, but the settlement provides that, if the agency fails to act within the specified time, the ingredient is deemed approved. This is an unworkable mechanism.

DRAFT

4. Local-State Preemption/Federalism

Issues: 1) To what extent should federal standards and procedures preempt state law in the tobacco area?

Is it desirable to have separate standards and enforcement under federal and state law?

If separate state standards are permitted, could they be limited to provisions that are more restrictive than federal standards, i.e. federal standards would set the floor?

2) Do any of the provisions violate state sovereignty?

Background: The proposal is inconsistent in its statements about preemption although it appears to modify existing standards at least under current FDCA law and, perhaps, under other federal statutes. Under current law regarding preemption for devices under the FDCA, for example, certain state laws are preempted unless the state obtains an exemption from preemption. The proposal appears (i) to modify FDA's ability to grant exemptions and (ii) to heighten the burden on states seeking exemptions. The proposal appears to leave unaffected tobacco exclusion provisions in other statutes, such as the Federal Cigarette Labeling and Advertising Act, the Hazardous Substance Act, and the Toxic Substances Control Act.

Significant Relevant Considerations:

1) Preemption: First, any preemption changes should be no more limiting on law enforcement than existing law. Second, there should be no federal preemption under the FDCA of state tort actions relating to tobacco products. Third, from a public health perspective, it would be preferable, if Constitutional, to have federal regulations establish the floor, with states free to be more restrictive if they so choose in order to protect public health. Fourth, federal preemption is appropriate to maintain a uniform national standard in the areas of labeling and warnings. Fifth, consideration should be given to repealing exclusions for tobacco in the Federal Hazardous Substance Act and the Toxic Substances Control Act.

2) Federalism: In its recent ruling on the Brady bill, the Supreme Court significantly limited the authority of the federal government to direct state official to administer or enforce a federal regulatory program. Thus, any provisions that anticipate state involvement in administration or enforcement should be evaluated as to whether they exceed the limits established by the Supreme Court.

7. LICENSING

The proposed settlement creates a licensing scheme for tobacco retailers that is intended to be administered by both federal and state authorities. Which level of government actually bears the responsibility for overseeing the program is unclear and needs to be clarified in any legislative language.

Licensing tobacco retailers is considered an important element of any comprehensive tobacco control effort. The ability to revoke a license and prevent a retailer from selling cigarettes or spit tobacco products is a powerful enforcement tool. FDA's objective is to be able to revoke a license if a retailer repeatedly sells tobacco products to minors. FDA is less interested in bearing the considerable responsibility for administering the licensing regime for more than 500,000 tobacco retailers.

According to SAMHSA, about thirty states have tobacco licensure requirements. There have been problems reported with the accuracy of retailer lists compiled by the states. Whatever current problems exist could probably be corrected with adequate resources.

Ideally, a licensing program would be administered by the states under guidelines established by the federal government. In this system, repeated violations of the federal prohibition against the sale of tobacco products to minors would trigger revocation of the retailer's license to sell the products. Further legal research is needed to ensure that this combined federal/state program can be done.

There are two other concerns raised by the licensing provision in the settlement. First, under the deal a license could only be revoked after ten illegal sales to minors in a two year period. This is an ineffective provision because it is extremely unlikely that ten compliance checks could be conducted on a single retailer in a two year time frame. Second, the settlement imposes a maximum penalty of $50,000 on a corporation. FDA has been considering a "chain-based" enforcement strategy that could enable the agency to take action against regional or national chains that repeatedly sell tobacco products to minors. The monetary limit in the settlement is significantly lower than the $1 million penalty FDA has the authority to impose under the civil money penalty provisions of the Food, Drug, and Cosmetic Act.

DRAFT

8. Civil Liability/Punitives/Immunity/Class Actions

Issues: Whether the incentives created by these provisions will have the appropriate public health result, and whether it is appropriate to settle existing actions now.

Background: Under the settlement, current Attorney General actions, parens patriae, and class actions would be resolved by agreement and there would be no future prosecution of such actions, either for past or future conduct. Punitive damages for past conduct would be prohibited. The companies would pay a set amount each year to cover the cost of any judgments. The allocation of annual payments among manufacturers is unclear. If the annual payment is more than judgments entered, the money would be used for public health programs. Limits are imposed on the amount of damages that can be paid out each year. In addition, any part of an individual judgment that exceeds $1 million will be paid only if all judgments under $1 million have been paid. The extent of funds available to pay judgments, and how judgments would be prioritized is unclear.

Significant Relevant Considerations:

- Policy determinations need to be made regarding the relative importance of: compensating individual consumers; punishing companies; deterring companies; creating a fund for public health programs.

- A great number of risks and variables could affect the potential amount of the liability being settled. One significant unknown is the content of undisclosed tobacco company documents. The settlement would end numerous lawsuits at a time when many documents are still being withheld. Although plaintiffs' likelihood of success is uncertain, it is possible that documents could come to light that would warrant imposition of greater penalties than contemplated by this agreement.

- It is not clear that all of these restrictions are necessary to achieve tobacco "peace." The elimination of both punitive damages and class actions and other consolidation mechanisms is a significant concession, and should be carefully evaluated.

- The settlement imposes limits on lawsuits involving future action by the tobacco companies. This limitation may not create appropriate deterrence effects on future conduct, and could be determinental to public health.

- FDA has traditionally opposed limits on tort liability because such liability has provided a separate system for consumer protection; the settlement could significantly reduce the deterrent effect of tort law with respect to tobacco products.

DRAFT

10. LOOK-BACK

Issue: Does the look-back provision act as an appropriate incentive for companies to reduce youth smoking?

Considerations: The proposed settlement contains a look-back provision with the stated purpose of providing economic incentives to tobacco firms to achieve "dramatic and immediate reductions in the number of underage consumers of tobacco products." Manufacturers would face a surcharge if tobacco-use reduction targets were not met- computed by comparing actual underage tobacco use with targeted reduction percentages. Manufacturers could petition FDA for partial abatement (75%) of the surcharge if they act in good faith (comply with the Act).

The proposed surcharge would be small in terms of the price of a pack of cigarettes (8 cents per pack)- due in part to a $2 billion cap-and with a 75% abatement would result in only 2 cents per pack. In addition, the cost would be passed on the customers. This amount of penalty is not likely to provide a strong incentive for companies to reduce youth smoking. Moreover, because the penalty is assessed industry wide, and not on a company-by-company basis according to each firms youth sales, there exists no incentive for any one company to take extraordinary action to reduce its own youth market. This "free-rider" nature of the penalty is perhaps the most important aspect that must be modified.

The look back provision is based on the principle that the penalty should reflect the present discounted value of the profits earned by attracting youth smokers over and above the targeted number. But under those conditions it merely makes the industry indifferent to whether it meets the target or not. A larger penalty is required to achieve deterrence.

Options- In order to provide a proper penalty one or more of the following could be done:
(1) Instead of setting the penalty at 1-for-1, make it a multiple of the profits - for example, the traditional treble damages.
(2) Instead of computing the fine on an industry basis, the fines should be levied on a firm-by-firm basis to create the right incentives and to avoid the "free-rider" problem.
(3) The look-back provision should be treated as a fine or penalty and not as a payment. This would insure that the amounts would not be tax deductible.
(4) Don't dilute the penalty with abatements, either eliminate or greatly reduce the abatement or make it adjustable to create the proper incentives.
(5) Instead of a one-size-fits-all penalty, structure the costs so that the penalty is lower the closer the companies get to the reduction targets. and/or
(6) The penalty should not be reduced to avoid double counting. As it is now devised, the companies pay only once for the profits over time from each child. If, however, they were required to pay each year the child continued to smoke, then the incentive would exist to not induce the child to start and to convince him not to continue each year.

11. ANTITRUST

Issue: Are there elements of the settlement that promote collusion among the companies?

Consideration: The companies are required to make substantial annual payments and they are expected to collect those payments from smokers in the form of higher prices. By this device and others, they are encouraged to work together to achieve this goal. This and other collusion-facilitating aspects of the settlement, such as the ban on advertising and the restrictions on entry, will probably lead to a consolidation of market power and will most likely make the major tobacco companies far better off financially than they would be in the absence of a settlement.

As noted in another paper, FTC economists fear that the inspired collusion will lead to higher prices than mandated. To the extent that the settlement facilitates cooperative price fixing (it has language calling for an antitrust exemption), discourages entry, reduces advertising which largely leads to brand substitution, and raises the costs of output expansion, it could lead to price increases greater than the excise tax equivalent of the industry payment. Of course, this higher price would directly affect youth smoking by depressing the numbers of young people who will start smoking, and as such is a positive health result.

Thus, a greater than 1-for-1 pass through of industry payments could lead to a rise in industry profits, which would be incrementally taxed at only 25%.

Although the result will be higher prices which will likely lead to fewer smokers, economists generally consider collusion, per se, to be an inefficiency in the system, leading to other market ills.

DRAFT

AGRICULTURAL ISSUES

The proposed settlement is silent about the impact of the settlement on farmers and the rural economy in general. Yet, this is clearly an issue that Congress will address if any settlement proposal receives serious consideration on the Hill. A number of congressional Democrats and GOP Rep. Thomas Bliley have all signaled their intent to see that farmers' interests are taken into account. The depth of feeling on these issues should not be underestimated: tobacco is a powerful cultural force in the tobacco states (60,000 small farms) and its economic payoff -- as a cash crop, the net income from tobacco for a farmer is estimated at 20 to 25 times greater than soybeans -- is significant to the individuals involved.

In the White House meeting, Gov. Jim Hunt summarized the farmers' concerns as threefold:

- Maintain a market for tobacco products, i.e., as much financial stability as the companies are getting from the settlement
- Receive commitments from companies to buy certain amount of tobacco each year
- Get one-time payout to farmers if the equity of their tobacco allotments is reduced by reduced consumption

The Farm Bureau has floated a proposal for farmers to receive a one-time payout of $7 billion to take into account the loss of equity as farmers' tobacco allotments lose value.

Considerations

Inherent contradictions/tensions mark any serious attempt to address farmers' concerns.

o Maintaining market stability for farmers clashes head-on with a public health goal of reduction in use of tobacco products.

o Maintaining an export market for U.S. tobacco clashes head-on with efforts by U.S. to support tobacco control efforts of other countries.

o Replacing tobacco with other crops clashes head-on with reality no other crop can offer anywhere near the economic return. (In White House meeting, crop replacement was never mentioned by farmers as a real possibility).

DRAFT

Minorities and Special Populations

Background:
The proposed Agreement does not adequately address minority communities. Minority groups and other special populations suffer a disproportionate burden of tobacco-related disease and are among the greatest users of tobacco products. Nationally, black men are approximately 50% more likely to die of lung cancer than are white men. Smoking rates are highest among American Indian/Alaskan Natives (42%) and blacks (27%), as well as for those, regardless of race, who are living below the poverty level (35%).

Because of these differentials, minorities and special populations are the most likely groups to be affected by changes in tobacco control policies, such as those contained in the proposed Agreement. These changes can be expected to have a positive effect, provided that assurances are given that the programs and other benefits actually reach the communities most at risk. However, minority communities are often dependent on the tobacco industry for philanthropic support of civic, cultural and community activities. Accordingly, because of this heightened dependence on tobacco industry largesse, minority communities may experience a disproportionate adverse economic effect.

Issues Deserving Special Consideration:

- **Full Access to Programs and Services:** Minority groups and other special populations need to be assured full access to targeted, community-appropriate programs, media and smoking cessation services, particularly so that cost is not a barrier to accessing cessation services.

- **Research Focused on Racial and Gender Differences:** Tobacco research programs should explicitly address gender and racial differences in tobacco use and its sequellae. Inclusion of representative researchers should be emphasized.

- **Replacement Sponsorship:** Because minority communities are disproportionately dependent upon tobacco industry largesse and philanthropy, settlement funds allocated for replacing tobacco industry sponsorship should extend beyond sports sponsorship and include sponsporship for community, cultural and civic events.

- **Governance and Decision-making**: Explicit involvement of minority and ethnic communities is needed in governance and decision-making bodies established as a result of the proposed Agreement. In particular, the ability of communities to create more protective tobacco control ordinances must not be pre-empted.

- **Inclusion of Tribes:** In addressing Tribal issues, the proposed Agreement uses a formula based on tribal population as percent of state population. This does not provide adequate funds for successful program implementation, especially considering that Native Americans experience the nation's highest tobacco use rates.

Draft
(revised)

14. ADVERTISING PROVISIONS

The settlement generally codifies the advertising restrictions in FDA's final rule and thus removes the current uncertainty regarding the legal validity of those restrictions. The settlement makes several other additions that would strengthen the effect of the advertising provisions including a ban of all outdoor tobacco advertising and advertising on the Internet. The provisions concerning point of sale advertising, which limit the number of signs and restrict their location and size, offer a public health benefit by closing an important avenue of appeal to young people in retail establishments. Perhaps of greatest importance, the settlement would incorporate the advertising and marketing provisions in consent orders with the States that will be signed by the participating companies, so that, at least theoretically, those companies would be bound by the restrictions regardless of legal challenges (for example, by the advertising industry). However, it is unclear whether this approach would be constitutional.

Many of the remaining provisions, such as the elimination of human and cartoon images from advertisements in adult publications and in adult facilities, are of little value and merely reflect the industry's current practice (for example, the recent announcement that Cool Joe Camel is being retired from the marketing of Camel cigarettes by R.J. Reynolds). While the settlement's ban of direct and indirect payments for tobacco product placement in movies, television programs, and video games and its prohibition of payments that "glamorize" tobacco use sound positive, these provisions are of little worth because they are largely unenforceable.

The settlement preserves the ability of the industry to continue using the terms "light" and "low tar" as descriptors of existing and future brand lines. These terms, adopted by the industry in the 1970's, are very problematic because they were used to persuade millions of smokers that these products were in fact safer than so-called full strength cigarettes and are widely believed to have kept many smokers from quitting. These products now also comprise 71 percent of the American market. We have a substantial body of data that show that there is in fact a significantly increased risk of disease from these "light" and "low tar" products. The settlement thus preserves the industry's ability to use terms in its advertising that are now known to be false and misleading to the public and prohibits FDA from taking action against such advertising under its current authority in the Food, Drug, and Cosmetic Act. The only action the settlement allows FDA to take is to require a disclaimer stating that the products may not be less hazardous, but such disclaimers are ineffective with consumers.

DRAFT

Tobacco-Related Research

Summary of Workgroup Report
August 1, 1997

I. Purpose

As new resources for tobacco control become available from HHS agencies, state governments, and possibly the tobacco industry, a robust, comprehensive, and well-funded tobacco research program is essential to inform the development of new federal and state policies and guide the use of these public and private funds.

II. Priorities

"Tobacco-related medical research" is defined as research related to reducing tobacco use and reducing the burden of diseases caused by tobacco. A comprehensive research program should examine tobacco's impact on health, disease and quality of life, and include studies from six research categories defined by the Department as biomedical, clinical, behavioral, health services, public health and community, and surveillance/epidemiological research. Research must address issues at the national, state, local, and individual levels, and include studies of tobacco use among both youth and adults. Prioritization of research areas and the allocation of funds should be guided by the overriding principles of reducing tobacco use and reducing the burden of tobacco-related disease on society.

III. Funding

Research funding should be commensurate with the burden of disease and disability caused by tobacco use. The proposed settlement contains four potential funding sources, including 1) funds for activities to reduce tobacco usage, 2) funds for prevention and cessation research, 3) the Tobacco Use Cessation Trust Fund, and 4) the Public Health Trust Fund (PHT).

IV. Governance and Accountability

The PHT will be operated as an endowment fund, and the investment income from the fund will define the annual expenditures for tobacco-related research. Specifically, full capitalization of the trust fund should be achieved over a three year rather than an eight year period. A Presidentially appointed board of trustees, representing the interests of both the scientific and lay communities, should oversee the investment and fund disbursal of the PHT. Specific protections are needed to prevent new research funds from supplanting Congress' current appropriations to agencies engaged in tobacco-related research.

DRAFT

HEALTH INVESTMENTS

Summary of Workgroup Report
August 1, 1997

The charge of this workgroup is to develop appropriate priorities for Departmental spending of the Tobacco Settlement's unallocated, or residual, funds. Options focus on promoting health and quality of life by fostering prevention, control, and treatment of diseases, and closing gaps in health status.

I. Principles Guiding Health Investment Trust Fund Utilization

A. The funds will be used for health-related purposes.
B. Funds will be directed to priority populations in order to reduce disparities.
C. A balance will be struck between strengthening existing efforts and establishing new initiatives.
D. Funds may not be used to supplant existing expenditures.
E. Funding decisions will be flexible in order to adjust for the uncertainty of this funding stream over time, and for changes in health priorities.
F. The feasibility of investing of Trust Fund monies will be investigated.

II. Proposed Options For Funding ($2-5 billion per option per year)

A. Pre to Three Program - Improving Prenatal Care and the Health Status of Children 0-3

This program would incorporate, and expand on, all 4 themes of the Children's Health Initiative and the relevant principles of the Department's Race Initiative for pregnant women and children 0-3 years old.

- Insurance expansion for pregnant women and children 0-3
- Outreach to Medicaid eligible pregnant women and children 0-3
- Expanded Healthy Start quality health care (Incorporating Health Home concept)
- Community-based programs for pregnant women and children 0-3 (Including developmental disabilities prevention, substance abuse and mental health services, immunization, injury prevention and screening programs)

B. School-Based Health Program

This program would expand the capacity of communities to provide school-based and school-linked health education and health services in areas of highest need.

C. Expanded Medicare Options

This program would include such features as grants to states for home and community-based care, reduced or eliminated 2 year waiting period for Medicare for the disabled, expanded respite care benefit, and cardiovascular disease prevention efforts.

D. Health Programs for Indian Tribes

This program would target urban Indian health, injury prevention, contract health services, women's and elder health, mental health services, inhalant abuse, oral health, diabetes prevention, sanitation facilities construction, maintenance and improvement, health care facilities construction, and tribal contract support.

F. Children's Health Initiative (Unchanged from its current form)

III. Accountability and Effectiveness

The success of these programs will hinge on the ability to analyze their effectiveness quickly, and modify them efficiently in order to keep pace with prevalent, often rapidly changing, health needs. Currently available monitoring systems are either too crude, or too limited in their scope, to effectively handle analysis of the proposed multi-billion dollar programs. Therefore, in addition to the programs listed above, Tobacco Settlement funds will be used to incorporate the latest scientific methods into surveillance and data analysis systems. Research into measures of quality care and cost-effectiveness also will be funded, and results will be incorporated into the proposals to ensure the use of relevant state-of-the-science health and financial outcomes measures.

IV. Governance

Funds will be placed in a trust fund(s) designated the "Health Investments Trust Fund(s)." A Board of Trustees with balanced membership from government, scientific, academic and lay communities, will be appointed by the President to oversee the dispersal of funds. An outside board will review Trust Fund activities on a regular basis.

DRAFT

SMOKING CESSATION & PUBLIC EDUCATION

Summary of Workgroup Report
August 1, 1997

The Workgroup believes effective programs to reduce tobacco use require a concerted, coordinated and synergistic effort at the national, state and community level. Programs should be targeted at both adult and youth tobacco users and non-users and at the environmental and social factors that encourage and support the use of tobacco. The desired outcomes of these programs are to prevent young people from starting to use tobacco, to help current tobacco users to quit, to protect the health of non-smokers by eliminating exposure to ETS, and to change the social and environmental factors that encourage and support the use of tobacco. Comprehensive programs based on these principles and funded at adequate levels have been shown to be effective in reducing per capita tobacco consumption.

I. Options and Recommendations for Use of Settlement in Smoking Cessation & Public Education

A comprehensive national and state level tobacco control program is proposed. It expands the range and intensity of existing programs and initiates new programs to fill the gaps and meet the needs of the nation. The program components include media, state/local programs, programs for special populations, school programs and cessation interventions, and includes surveillance and evaluation systems capable of not only assessing program outcomes and monitoring program performance but also of holding the tobacco industry accountable for its continued role in maintaining the use of tobacco among youth.

II. Funds Available

▸ Reduction in Tobacco Usage	$ 5.325 billion
▸ Programs Like ASSIST	$ 3.0 billion
▸ Tobacco Use Cessation Trust Fund	$ 35.5 billion
▸ Public Education	$ 12.5 billion
▸ Teams Fund	$ 0 .75 billion
▸ Public Health Trust Fund	$ 25 billion
▸ Prevention/Cessation Research	$ 2.5 billion

III. Sufficiency of Funds

While some line items allocations in the proposed Settlement are not sufficient for all above noted components, funds can be re-directed between these categories to adequately fund a comprehensive program.

IV. Key Issues to be Addressed and Areas for Potential Modification of Settlement

- **Administration of Settlement Funds.** The division of responsibility as outlined would present unique issues and challenges to DHHS for the implementation of a coordinated, synergistic effort.
- **Funding for ASSIST Like Programs.** The ASSIST level of funding is approximately $1.2 million per state which will not provide for comprehensive programs within all states.
- **Additional Programs Are Needed.** The overall program should be considered as a nationwide effort involving activities through multiple agencies and organizations at all levels.
- **The Balance Between Media, Cessation, and Public Education Programs.** The funding levels in the Settlement are heavily weighted to cessation and media. A better balance is needed.
- **Implementation of the Tobacco Use Cessation Funds.** The Settlement proposes a program that would enable most tobacco users to receive assistance tailored to the needs to the individual smokers, and not limited to a single attempt. There are concerns about the value of spending the Settlement's proposed $1 billion on a federal policy to reimburse insurers for cessation interventions.
- **Appropriate Allocation of Resources for Cessation and Public Education to Indian Tribes.** The Settlement treats Tribes like states, but the formula is based on tribal population as percent of state population, thus not providing adequate funds for successful program implementation.

DRAFT

17. National Protocol/Consent Decrees

Issue: Whether the national protocol and consent decrees are legally permissible ways to help ensure compliance with the provisions of the settlement.

Background: The settlement has provisions for a "binding and enforceable national tobacco control Protocol" and consent decrees between the States and the participating tobacco companies. These provisions are very vague, but information in the settlement and from the negotiators indicates that they intended that the national protocol and each state consent decree would contain certain provisions of the settlement and be enforceable as contracts by the respective states. They are to allow the States to have independent enforcement authority, particularly in the event that enacted legislation is modified by a later Congress, or particular provisions are struck down on Constitutional grounds. In addition, some of the advertising restrictions that go beyond the FDA regulations and may be more vulnerable to Constitutional challenge, would only be in the protocol/consent decrees.

Significant Relevant Considerations:

•The national protocol and consent decrees do not appear to be effective mechanisms that would allow the federal government to direct enforcement activities, and conduct a national program to reduce tobacco use by young people. Individual consent decrees would be enforceable only by the relevant signatory states in the jurisdictions in which they were entered, and not by the federal government.

•The federal government could not direct state enforcement activities conducted pursuant to the consent decrees. Federal legislation will need to be the source of obligations enforceable by federal action.

•The consent decrees/national protocol should be considered when evaluating the preemption provisions of the settlement, so as to ensure that the preemption provisions do not inappropriately constrain the states from enforcing the consent decrees/national protocol.

•The settlement's assumption that the use of consent decrees and/or a national protocol would eliminate the possibility of Constitutional challenge to the advertising provisions may be invalid. Moreover, if certain of the advertising restrictions are in federal law, they are particularly vulnerable to Constitutional challenge. On the other hand, if certain advertising restrictions (e.g., Internet advertising) are not in federal law, they will be less Constitutionally vulnerable, but may be broadly unenforceable and will likely be beyond federal enforcement reach.

DRAFT

18. ACCESS RESTRICTIONS: KEEPING TOBACCO OUT OF CHILDREN'S HANDS

FDA issued a number of access restrictions in the final rule including setting 18 as the federal minimum age of sale, requiring photo ID, eliminating free samples in person and through the mail, eliminating the sale of single cigarettes or "kiddie packs" (packs of less than 20 cigarettes), and limiting vending machines and self-service displays only to those areas where no one under 18 is present.

The proposed settlement seems to intend to codify all of the access measures in the final rule although the language used in the document is somewhat vague. (We have been told by one of the leading negotiators that the industry has agreed to use the exact language of the final rule and to include all the access provisions.)

In addition to incorporating the access provisions from the final rule, the settlement goes beyond the final rule and eliminates all vending machines and prohibits mail order sales. Further, in facilities where anyone under 18 may enter, the settlement requires all tobacco products to be placed out-of-reach of consumers, or, if on the counter, to not be visible or accessible to consumers. These are positive enhancements.

On the other hand, the proposed settlement freezes for five years any additional rule making. In the event that tobacco companies spend that period focusing on getting young people between the ages of 18 and 21 to begin smoking or using smokeless tobacco, the Agency would be blocked during this period from raising the federal minimum age.

Several options could be considered. First, the actual language from the final rule should be used rather than the vague language in the settlement. Second, it is worth considering whether to eliminate this adult-only exception altogether and thereby prohibit all self-service displays. (Since the final rule was issued, a number of tobacco companies and retailer organizations have been interested in greatly expanding the types of places that would be considered adult-only. This option would simplify matters and prevent the expansion of such facilities beyond what the agency intended.) Third, the freeze could be eliminated or limited to two years.

DRAFT

19. PROTECTING THE GOVERNMENT'S ABILITY TO RESPOND TO CHANGING CIRCUMSTANCES

FDA currently has the ability through informal rulemaking and other mechanisms specified in the Federal Food, Drug, and Cosmetic Act to impose additional requirements on cigarettes and smokeless tobacco should the Agency find that they are necessary to protect children and adolescents from tobacco.

For example, the Agency now has the ability to raise the minimum age of sale from 18 to 19, 20, or 21 if it found that industry practices were resulting in dramatic increases in new smokers among these groups. Or, it could limit new types of advertising not currently employed by the industry if it found that these forms of advertising were influencing children's tobacco use. Additionally, the Agency could limit the types of retailers that could sell tobacco, add new warnings to the packaging or labeling of tobacco products, or require plain packaging. The Agency held back from taking these steps in the final regulation but always recognized that it had the ability to take such actions in the future.

Informal rule making also could be employed quickly and efficiently to correct or clarify any provisions in the final rule. If, for example, the exemption from advertising restrictions for "adult-only" publications was being vastly overused to permit all forms of advertising in publications read by young people, the Agency could eliminate this exemption. Furthermore, in the event that FDA found that other tobacco products such as cigars met the definition of a drug or device under the Act, the Agency could assert jurisdiction over them and subject them to the same regulations as cigarettes and smokeless tobacco.

The government's flexibility to respond to new tobacco industry practices or other factors resulting in increased tobacco use among young people is vital to the Administration's long-term ability to protect young people from tobacco. It gives the tobacco industry an enormous advantage if the government is unable to issue new rules as needed.

Under the proposed settlement, the Agency is frozen for five years from taking any additional action except in "extraordinary conditions." This freeze will permit the tobacco industry to initiate new access or advertising practices secure in the knowledge that the government is prevented from doing anything to respond for a period of five years. Five years is a considerable length of time in the advertising world. (For example, from the time R.J.Reynolds introduced Joe Camel until it Camel's popularity among children soared was only a few years.)

While the five-year-freeze is specified in the proposed settlement, the document does not affirm the Agency's ability after five years to issue new regulations. If legislation incorporates all of the current regulations but fails to expressly reserve to the Agency the ability to issue new regulations through informal rule making and other mechanisms specified in the statute, it might give the impression that Congress has identified all the restrictions it believes are necessary and that FDA cannot issue take any additional actions.

Options for addressing the above concerns include: limiting the freeze to two years, eliminating the freeze altogether, and expressly reserving for FDA the authority to issue new rules.

DRAFT

20. COUNTER-ADVERTISING: REACHING YOUNG PEOPLE

Counter-advertising is a vital element of any comprehensive tobacco control program. It is not enough to reduce the barrage of advertising and promotional messages young people receive that encourage them to smoke cigarettes or use smokeless tobacco. Young people need positive messages to help them reject pro-tobacco messages and to choose not to use tobacco. In addition, counter-advertising is useful in motivating people to quit smoking and to foster support for smoke-free environments. The most effective nationwide counter-advertising program is one that combines multi-media efforts with school-based and community-based programs. It should have national, state, and local components. (To this end, CDC is including a $50 million counter-advertising component to its 'FY'98 budget request.)

The Food, Drug, and Cosmetic Act (section 518(a)) provides a mechanism for FDA to require manufacturers to notify users and potential users of an unreasonable risk posed by a product. In the preamble to the final rule, FDA indicated that this notification process might be an appropriate means to require tobacco manufacturers to fund multi-media campaigns to educate children and adolescents about the risks associated with tobacco products. The process for requiring companies to undertake this effort would consist of the Agency notifying companies of its intent to require such action, providing an opportunity for a hearing, and, if necessary, imposing a "notification order." The Agency has not yet taken this action.

The proposed settlement provides for the establishment of a public education program which the industry would fund annually for $500 million. It does not appear to place restrictions on the type of educational messages that could be developed. It authorizes the Secretary of Health and Human Services to establish a public education program to "discourage and deglamorize the use of tobacco products," and to make grants to state health departments to assist in carrying out these programs. However, it seems to provide primary authority to an independent non-profit organization. It is unclear the extent to which the Secretary would oversee the counter-advertising program.

In the event that this settlement were finalized, it would seem to decrease the need for FDA to use its authority to require companies to fund an additional campaign. The amount of the funding, the immediacy of the availability of funds, and the lack of restrictions on the type of messages are clearly favorable.

Although $500 million is far more than the government has ever had to undertake counter-advertising, it may be somewhat less than the amount needed for a coordinated national/state/local campaign. (For example, if a national campaign were modeled on the Massachusetts' campaign, it would require approximately $600 million annually.)

Options to consider include: increasing to $600 million annually the amount of the counter-advertising campaign and, if an independent organization is formed to oversee the program, ensuring that such an organization receives overall direction or guidance from the Department. Alternatively, consideration should be given to having the program run by the Department so as to be able to coordinate media efforts with other prevention and cessation activities.

DRAFT

23. Enforcement/Penalties

Issue: Should enforcement mechanisms and penalty provisions in existing law be strengthened or otherwise be changed?

Background: Current enforcement authority is found in the Federal Food Drug and Cosmetic Act and Title 18 of the United States Code. In addition, states are required to enforce their laws concerning the sale of tobacco products to minors in order to receive federal substance abuse block grants. The proposed settlement contains certain new provisions, but is unclear as to whether existing penalty provisions would be retained, diminished, or enhanced.

Significant relevant considerations: Any proposal should clarify that existing sanctions and penalties are either retained or form a threshold for developing new, enhanced provisions. Unlike the proposal, any new provisions should not restrict broad-based action, such as enforcement against "chains" for sales violation, with an unduly low corporate cap. That is, the government should be able to combine the individual fines for a large number of violations against the same corporate entity without being limited by a maximum fine per company. The government may also want to use this settlement opportunity to enhance existing authority with other provisions, for example:

-- raising the FDCA civil money penalty maximum, currently $15,000 per violation, $1,000,000 per proceeding;

-- giving FDA full subpoena power; or

-- streamlining civil money penalty procedures to allow for ticketing by FDA. Currently, FDA must provide for an opportunity for a hearing before assessing a fine. It may be preferable to first issue a ticket and then provide an opportunity to appeal.

DRAFT

Monitoring, Evaluation, and Program Accountability

Background:
All proposed program efforts (i.e., media, community, school, cessation activities, and minors' access advertising restriction provisions) will require a comprehensive monitoring and evaluation system to assess program impact at the state, major metropolitan, and media market levels. Because the nature and complexity of these needs will place unprecedented and urgent demands on current systems, existing health information systems must be stregthened. Otherwise, it will not be possible to determine if intended public health effects are being achieved. New levels of monitoring and evaluation capacity at the Federal and State level are required, especially in view of the erosion in our public health infrastructure over the last two decades.

While the monitoring of adult smoking behaviors at the national and state levels, and of youth smoking at the national level is well established, major gaps in data collection and evaluation systems remain. Monitoring youth smoking is incomplete at the state level, and needs to be expanded to major media markets. Little infrastructure for evaluating the provision of cessation interventions exists, and mechanisms to hold the tobacco industry accountable (e.g., advertising that influences youth, or tactics that hamper effective minors' access restrictions) are needed.

Issues Deserving Special Consideration:

- **Expanding Current Survey Mechanisms.** Current monitoring and evaluation activities need to be expanded at the national, state, and local levels, as well as in major media markets, to incorporate: 1) tobacco-related knowledge, attitudes, and behaviors (e.g., detailed descriptions of brand preference, the incidence of initiation and cessation of various tobacco-use behaviors, and observation and reactions to both anti- and pro-tobacco media messages) among adults and youth; 2) exposures to both anti- and pro-tobacco programs and messages (e.g., anti-smoking advertisements, tobacco's portrayal on television and in the movies, attempts by the industry to circumvent advertising restrictions); 3) relevant policies, ordinances, and laws, and their enforcement; 4) biomarkers indicative of exposure to tobacco and tobacco smoke; and 5) current and future tobacco products' composition and design, including laboratory analyses of tobacco and tobacco smoke and their constituents in body fluids.

- **Coordination of Efforts.** The monitoring and evaluation system will need to function in a coordinated fashion. Currently most activities are being conducted by CDC, with SAMHSA, NIDA, FDA, NCI, and others also conducting monitoring and evaluation work.

- **Allocation and Sufficiency of Funding.** Funding for these activities should be assured and allocated separately from those allocated for research. Furthermore, CDC estimates that approximately $270 million annually will be needed to conduct the required activities.

- **Expedited Clearance Mechanisms.** The dynamic and rapid need for monitoring data will require expedited mechanisms for clearance of surveys and for funding of evaluation projects. Applied research projects to guide timely modification of intervention efforts also need expedited review and funding.

DRAFT

26. HEALTH CLAIMS

The proposed settlement envisions that conventional and so-called "less hazardous tobacco products" would be able to make health claims in labeling and advertising. The deal also preserves the industry's ability to make "light" and "low tar" claims as long as such claims are accompanied by a disclaimer elsewhere on the label or in an advertisement. Serious questions have been raised about the public health benefit of these provisions and about the wisdom of deciding this issue now (as opposed to letting FDA decide at a future time whether to permit these claims).

The first fundamental issue that must be addressed is whether claims should even be allowed for tobacco products that pose reduced risks but are still dangerous and addictive. There are some in the public health community who believe there is a role for such claims. However, important lessons from the history of "light" and "low tar" marketing efforts are quite relevant here. Filtered "light" cigarettes sold over the last 30 years may have reduced tar and nicotine deliveries, but there was no concomitant reduction in the death and disease associated with tobacco use as result of these marketing innovations (perhaps because smokers simply smoked more cigarettes or inhaled more deeply). As we look toward the next 30 years we must remember that every single cigarette on the market today, regardless of its nicotine level, is capable of both creating and sustaining addiction. It is arguable whether health claims should be permitted for innovations that may reduce the risk of products that nonetheless remain deadly and addictive.

The second fundamental issue is the vagueness of the health claims provision in the settlement. Under the deal, "scientifically-based health claims" would be permitted for "less hazardous tobacco products." These terms are not defined, hence there is no way to know what the negotiators meant. One party to the negotiations has stated that it would be up to FDA to determine what these terms mean. Until legislative language is drafted and enacted into law, it is unclear whether FDA would indeed have that discretion and authority.

The third fundamental issue raised by the settlement is the provision that allows claims for "less hazardous tobacco products" to be exempt from the advertising restrictions in the legislation if FDA finds that such advertising would reduce harm and promote public health. Even if FDA retains the discretion to make these determinations, the wisdom of the provision remains debatable.

The fourth fundamental issue is addressed in the "Advertising Provisions" analysis that discusses the impact of the "grand fathering" of certain "light" and "low tar" claims. As stated in that analysis, FDA would be unable to eliminate the use of these misleading terms as long as they were accompanied by relatively ineffective disclaimers.

DRAFT

AGRICULTURAL ISSUES

The proposed settlement is silent about the impact of the settlement on farmers and the rural economy in general. Yet, this is clearly an issue that Congress will address if any settlement proposal receives serious consideration on the Hill. A number of congressional Democrats and GOP Rep. Thomas Bliley have all signaled their intent to see that farmers' interests are taken into account. The depth of feeling on these issues should not be underestimated: tobacco is a powerful cultural force in the tobacco states (60,000 small farms) and its economic payoff -- as a cash crop, the net income from tobacco for a farmer is estimated at 20 to 25 times greater than soybeans -- is significant to the individuals involved.

In the White House meeting, Gov. Jim Hunt summarized the farmers' concerns as threefold:

- Maintain a market for tobacco products, i.e., as much financial stability as the companies are getting from the settlement
- Receive commitments from companies to buy certain amount of tobacco each year
- Get one-time payout to farmers if the equity of their tobacco allotments is reduced by reduced consumption

The Farm Bureau has floated a proposal for farmers to receive a one-time payout of $7 billion to take into account the loss of equity as farmers' tobacco allotments lose value.

Considerations

Inherent contradictions/tensions mark any serious attempt to address farmers' concerns.

o Maintaining market stability for farmers clashes head-on with a public health goal of reduction in use of tobacco products.

o Maintaining an export market for U.S. tobacco clashes head-on with efforts by U.S. to support tobacco control efforts of other countries.

o Replacing tobacco with other crops clashes head-on with reality no other crop can offer anywhere near the economic return. (In White House meeting, crop replacement was never mentioned by farmers as a real possibility).

Laura Emmett 06/16/97 01:14:32 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: TOBACCO MTG. TODAY IS CANCELLED.

We will probably reschedule for 2:00 on Wednesday, so try to hold this time and I will let you all know for sure later.

Message Sent To:

Michelle Crisci/WHO/EOP
Jennifer D. Dudley/WHO/EOP
Barbara D. Woolley/WHO/EOP
Anne E. McGuire/WHO/EOP
Daniel C. Tate/WHO/EOP
Tracey E. Thornton/WHO/EOP
Cathy R. Mays/OPD/EOP
Elizabeth Drye/OPD/EOP
Laura K. Capps/WHO/EOP
Michael Waldman/WHO/EOP
Lisa J. Levin/WHO/EOP
Emily Bromberg/WHO/EOP
Peter R. Orszag/OPD/EOP

Outline of Working Group Analyses

I. Brief description of issue area(s)

II. Public health/public interest goals (e.g., effect on children's smoking, adult smokers, addictiveness/safety of product, recovery of Medicaid costs, etc.)

III. Long-term analysis without a settlement

A. Current/Planned activities (expected benefits; timing; litigation risk)

B. Additional possible actions (expected benefits; pros and cons)

IV. Long-term analysis with a settlement

Outline of Working Group Papers on Baseline Activities

I. Brief description of issue area(s)

II. Public health/public interest goals (e.g., affect on kid smokers, adult smokers, addictiveness/safety of product, recovering Medicaid costs)

III. Actions absent a settlement

A. Current/Planned activities (expected benefits; timing; litigation risk)

B. Additional possible actions (expected benefits; pros and cons)

IV. Critical Issues

Erskine memo -- timetables change
First step is world without settlement -- get started
First meeting

- convene larger group (30 people)
- process and goals --
- convene working groups (assign leads)
    1. FDA regulation of product, access, and labeling
    2. Advertising restrictions / public education
    3. Environmental tobacco smoke
    4. Smoking cessation
    5. Farmers
    6. Liability and litigation

Also

-- CEA starts industry analysis (need CEA at meeting?)
-- USTR/HHS start review of interenational policy; trends (need USTR at meeting?)

- Ask for paper by (Monday?)

Advance work

- Bruce calls Kevin
- Jerry calls FDA, others
- Eliz calls treasury, OSHA

Pending work

- Principles

- When paper arrives
    - Drafting and enforcement issues in codifying a potential agreement
    - Analysis of specific settlement provisions

Erskine memo -- timetables change
First step is world without settlement -- get started
First meeting

- convene larger group (30 people)
- process and goals --
- convene working groups (assign leads)
    1. FDA regulation of product, access, and labeling
    2. Advertising restrictions / public education
    3. Environmental tobacco smoke
    4. Smoking cessation
    5. Farmers
    6. Liability and litigation

Also

-- CEA starts industry analysis (need CEA at meeting?)
-- USTR/HHS start review of interenational policy; trends (need USTR at meeting?)

- Ask for paper by (Monday?)

Advance work

- Bruce calls Kevin
- Jerry calls FDA, others
- Eliz calls treasury, OSHA

Pending work

- Principles

- When paper arrives
    - Drafting and enforcement issues in codifying a potential agreement
    - Analysis of specific settlement provisions

June 11, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Bruce Lindsey
Rahm Emanuel

SUBJECT: Tobacco Settlement Review Process

We have reached agreement with HHS on a process to review and evaluate the possible tobacco settlement with relevant agencies, to seek input from the public health community, and to present recommendations to the President. Our goal is to prepare a memo for the President later this month that: (1) defines the public health and public interest objectives of a global settlement; (2) weighs the settlement's strengths and weaknesses against those objectives and proposes possible modifications; (3) assesses the likely reactions of the public health community and other affected parties; and (4) lays out options for how to respond to a settlement announcement.

Interagency Review

This review will be carried out by (1) our existing tobacco group, which will examine the public health and liability issues, and (2) a DPC-NEC health care team led by Chris Jennings, which will assess how to spend recovered Medicaid revenues. These teams will look at the Administration's overall public health and public interest goals; what will happen with the proposed settlement, what will happen with no settlement; and what changes we might want in any global settlement.

o Public Health and Liability Team

We expect to receive a draft of the possible settlement documents tomorrow or Friday from Attorney General Mike Moore. We will hold a White House meeting Friday or Monday with representatives from the major agencies (HHS, Justice, Treasury, USDA, Labor, OMB) and White House offices (DPC, NEC, OVP, OSTP, Counsel, Leg. Affairs, Intergovernmental, Public Liaison) to begin review of these documents. The principal issues will be:

1. FDA regulation of product, access, and labeling
2. Advertising restrictions / public education
3. Environmental tobacco smoke
4. Smoking cessation

5. Farmers
6. Liability and litigation
7. Drafting and enforcement issues in codifying a potential agreement

We will ask these representatives to respond with preliminary recommendations by Thursday, June 19. At the same time, we will ask a smaller group of agencies (HHS, USTR, State, Commerce, NEC, NSC, DPC) for their views on U.S. responsibility in addressing the growth of smoking worldwide.

o Medicaid Spending/Children's Health Team

Chris Jennings' group (HHS, Treasury, Labor, OMB, DPC, NEC) will begin meeting tomorrow to explore options for using the Federal government's share of recovered Medicaid funds for health care investments. This is an effort we had already planned to undertake to evaluate Hatch-Kennedy or similar legislation.

Outreach

Over the next two weeks, we will reach out to public health organizations and individuals and to members of Congress. Key public health contacts include: Action on Smoking and Health; American Cancer Society; American Heart Association; American Medical Association; American Academy of Pediatrics; American Public Health Association; Americans for Nonsmokers' Rights; National Center for Tobacco-Free Kids; Dr. Kessler; and Dr. Koop. We will also meet with other affected parties (states, farmers, small businesses) as appropriate.

Schedule

We have planned the following schedule, but note that adherence to this timetable is highly dependent on agency cooperation.

June 12:	Teams begin meeting.
June 18:	Teams report back with initial findings and outstanding issues.
Week of June 16:	White House and HHS host meetings with public health groups.
Week of June 23:	Develop options for outstanding issues; hold principals meeting.
June 27:	Send memo to the President.

Mike Moore told us today that the parties to the negotiations will meet Monday and try to reach agreement by mid-week.

June 11, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Bruce Lindsey
Rahm Emanuel

SUBJECT: Tobacco Settlement Review Process

We have reached agreement with HHS on a process to review and evaluate the possible tobacco settlement with relevant agencies, to seek input from the public health community, and to present recommendations to the President. Our goal is to prepare a memo for the President later this month that: (1) defines the public health and public interest objectives of a global settlement; (2) weighs the settlement's strengths and weaknesses against those objectives and proposes possible modifications; (3) assesses the likely reactions of the public health community and other affected parties; and (4) lays out options for how to respond to a settlement announcement.

Interagency Review

This review will be carried out by (1) our existing tobacco group, which will examine the public health and liability issues, and (2) a DPC-NEC health care team led by Chris Jennings, which will assess how to spend recovered Medicaid revenues. These teams will look at the Administration's overall public health and public interest goals; what will happen with the proposed settlement, what will happen with no settlement; and what changes we might want in any global settlement.

o Public Health and Liability Team

We expect to receive a draft of the possible settlement documents tomorrow or Friday from Attorney General Mike Moore. We will hold a White House meeting Friday or Monday with representatives from the major agencies (HHS, Justice, Treasury, USDA, Labor, OMB) and White House offices (DPC, NEC, OVP, OSTP, Counsel, Leg. Affairs, Intergovernmental, Public Liaison) to begin review of these documents. The principal issues will be:

1. FDA regulation of product, access, and labeling
2. Advertising restrictions / public education
3. Environmental tobacco smoke
4. Smoking cessation

5. Farmers
6. Liability and litigation
7. Drafting and enforcement issues in codifying a potential agreement

We will ask these representatives to respond with preliminary recommendations by Thursday, June 19. At the same time, we will ask a smaller group of agencies (HHS, USTR, State, Commerce, NEC, NSC, DPC) for their views on U.S. responsibility in addressing the growth of smoking worldwide.

o Medicaid Spending/Children's Health Team

Chris Jennings' group (HHS, Treasury, Labor, OMB, DPC, NEC) will begin meeting tomorrow to explore options for using the Federal government's share of recovered Medicaid funds for health care investments. This is an effort we had already planned to undertake to evaluate Hatch-Kennedy or similar legislation.

Outreach

Over the next two weeks, we will reach out to public health organizations and individuals and to members of Congress. Key public health contacts include: Action on Smoking and Health; American Cancer Society; American Heart Association; American Medical Association; American Academy of Pediatrics; American Public Health Association; Americans for Nonsmokers' Rights; National Center for Tobacco-Free Kids; Dr. Kessler; and Dr. Koop. We will also meet with other affected parties (states, farmers, small businesses) as appropriate.

Schedule

We have planned the following schedule, but note that adherence to this timetable is highly dependent on agency cooperation.

June 12:	Teams begin meeting.
June 18:	Teams report back with initial findings and outstanding issues.
Week of June 16:	White House and HHS host meetings with public health groups.
Week of June 23:	Develop options for outstanding issues; hold principals meeting.
June 27:	Send memo to the President.

Mike Moore told us today that the parties to the negotiations will meet Monday and try to reach agreement by mid-week.

June 11, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Bruce Lindsey
Rahm Emanuel

SUBJECT: Tobacco Settlement Review Process

We have reached agreement with HHS on a process to review and evaluate the possible tobacco settlement with relevant agencies, to seek input from the public health community, and to present recommendations to the President. Our goal is to prepare a memo for the President later this month that: (1) defines the public health and public interest objectives of a global settlement; (2) weighs the settlement's strengths and weaknesses against those objectives and proposes possible modifications; (3) assesses the likely reactions of the public health community and other affected parties; and (4) lays out options for how to respond to a settlement announcement.

Interagency Review

This review will be carried out by (1) our existing tobacco group, which will examine the public health and liability issues, and (2) a DPC-NEC health care team led by Chris Jennings, which will assess how to spend recovered Medicaid revenues. These teams will look at the Administration's overall public health and public interest goals; what will happen with the proposed settlement, what will happen with no settlement; and what changes we might want in any global settlement.

o Public Health and Liability Team

We expect to receive a draft of the possible settlement documents tomorrow or Friday from Attorney General Mike Moore. We will hold a White House meeting Friday or Monday with representatives from the major agencies (HHS, Justice, Treasury, USDA, Labor, OMB) and White House offices (DPC, NEC, OVP, OSTP, Counsel, Leg. Affairs, Intergovernmental, Public Liaison) to begin review of these documents. The principal issues will be:

1. FDA regulation of product, access, and labeling
2. Advertising restrictions / public education
3. Environmental tobacco smoke
4. Smoking cessation

5. Farmers
6. Liability and litigation
7. Drafting and enforcement issues in codifying a potential agreement

We will ask these representatives to respond with preliminary recommendations by Thursday, June 19. At the same time, we will ask a smaller group of agencies (HHS, USTR, State, Commerce, NEC, NSC, DPC) for their views on U.S. responsibility in addressing the growth of smoking worldwide.

o Medicaid Spending/Children's Health Team

Chris Jennings' group (HHS, Treasury, Labor, OMB, DPC, NEC) will begin meeting tomorrow to explore options for using the Federal government's share of recovered Medicaid funds for health care investments. This is an effort we had already planned to undertake to evaluate Hatch-Kennedy or similar legislation.

Outreach

Over the next two weeks, we will reach out to public health organizations and individuals and to members of Congress. Key public health contacts include: Action on Smoking and Health; American Cancer Society; American Heart Association; American Medical Association; American Academy of Pediatrics; American Public Health Association; Americans for Nonsmokers' Rights; National Center for Tobacco-Free Kids; Dr. Kessler; and Dr. Koop. We will also meet with other affected parties (states, farmers, small businesses) as appropriate.

Schedule

We have planned the following schedule, but note that adherence to this timetable is highly dependent on agency cooperation.

June 12:	Teams begin meeting.
June 18:	Teams report back with initial findings and outstanding issues.
Week of June 16:	White House and HHS host meetings with public health groups.
Week of June 23:	Develop options for outstanding issues; hold principals meeting.
June 27:	Send memo to the President.

Mike Moore told us today that the parties to the negotiations will meet Monday and try to reach agreement by mid-week.

June 11, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Bruce Lindsey
Rahm Emanuel

SUBJECT: Tobacco Settlement Review Process

We have reached agreement with HHS on a process to review and evaluate the possible tobacco settlement with relevant agencies, to seek input from the public health community, and to present recommendations to the President. Our goal is to prepare a memo for the President later this month that: (1) defines the public health and public interest objectives of a global settlement; (2) weighs the settlement's strengths and weaknesses against those objectives and proposes possible modifications; (3) assesses the likely reactions of the public health community and other affected parties; and (4) lays out options for how to respond to a settlement announcement.

Interagency Review

This review will be carried out by (1) our existing tobacco group, which will examine the public health and liability issues, and (2) a DPC-NEC health care team led by Chris Jennings, which will assess how to spend recovered Medicaid revenues. These teams will look at the Administration's overall public health and public interest goals; what will happen with the proposed settlement, what will happen with no settlement; and what changes we might want in any global settlement.

o Public Health and Liability Team

We expect to receive a draft of the possible settlement documents tomorrow or Friday from Attorney General Mike Moore. We will hold a White House meeting Friday or Monday with representatives from the major agencies (HHS, Justice, Treasury, USDA, Labor, OMB) and White House offices (DPC, NEC, OVP, OSTP, Counsel, Leg. Affairs, Intergovernmental, Public Liaison) to begin review of these documents. The principal issues will be:

1. FDA regulation of product, access, and labeling
2. Advertising restrictions / public education
3. Environmental tobacco smoke
4. Smoking cessation

5. Farmers
6. Liability and litigation
7. Drafting and enforcement issues in codifying a potential agreement

We will ask these representatives to respond with preliminary recommendations by Thursday, June 19. At the same time, we will ask a smaller group of agencies (HHS, USTR, State, Commerce, NEC, NSC, DPC) for their views on U.S. responsibility in addressing the growth of smoking worldwide.

o Medicaid Spending/Children's Health Team

Chris Jennings' group (HHS, Treasury, Labor, OMB, DPC, NEC) will begin meeting tomorrow to explore options for using the Federal government's share of recovered Medicaid funds for health care investments. This is an effort we had already planned to undertake to evaluate Hatch-Kennedy or similar legislation.

Outreach

Over the next two weeks, we will reach out to public health organizations and individuals and to members of Congress. Key public health contacts include: Action on Smoking and Health; American Cancer Society; American Heart Association; American Medical Association; American Academy of Pediatrics; American Public Health Association; Americans for Nonsmokers' Rights; National Center for Tobacco-Free Kids; Dr. Kessler; and Dr. Koop. We will also meet with other affected parties (states, farmers, small businesses) as appropriate.

Schedule

We have planned the following schedule, but note that adherence to this timetable is highly dependent on agency cooperation.

June 12:	Teams begin meeting.
June 18:	Teams report back with initial findings and outstanding issues.
Week of June 16:	White House and HHS host meetings with public health groups.
Week of June 23:	Develop options for outstanding issues; hold principals meeting.
June 27:	Send memo to the President.

Mike Moore told us today that the parties to the negotiations will meet Monday and try to reach agreement by mid-week.

June 11, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Bruce Lindsey
Rahm Emanuel

SUBJECT: Tobacco Settlement Review Process

We have reached agreement with HHS on a process to review and evaluate the possible tobacco settlement with relevant agencies, to seek input from the public health community, and to present recommendations to the President. Our goal is to prepare a memo for the President later this month that: (1) defines the public health and public interest objectives of a global settlement; (2) weighs the settlement's strengths and weaknesses against those objectives and proposes possible modifications; (3) assesses the likely reactions of the public health community and other affected parties; and (4) lays out options for how to respond to a settlement announcement.

Interagency Review

This review will be carried out by (1) our existing tobacco group, which will examine the public health and liability issues, and (2) a DPC-NEC health care team led by Chris Jennings, which will assess how to spend recovered Medicaid revenues. These teams will look at the Administration's overall public health and public interest goals; what will happen with the proposed settlement, what will happen with no settlement; and what changes we might want in any global settlement.

o Public Health and Liability Team

We expect to receive a draft of the possible settlement documents tomorrow or Friday from Attorney General Mike Moore. We will hold a White House meeting Friday or Monday with representatives from the major agencies (HHS, Justice, Treasury, USDA, Labor, OMB) and White House offices (DPC, NEC, OVP, OSTP, Counsel, Leg. Affairs, Intergovernmental, Public Liaison) to begin review of these documents. The principal issues will be:

1. FDA regulation of product, access, and labeling
2. Advertising restrictions / public education
3. Environmental tobacco smoke
4. Smoking cessation

5. Farmers
6. Liability and litigation
7. Drafting and enforcement issues in codifying a potential agreement

We will ask these representatives to respond with preliminary recommendations by Thursday, June 19. At the same time, we will ask a smaller group of agencies (HHS, USTR, State, Commerce, NEC, NSC, DPC) for their views on U.S. responsibility in addressing the growth of smoking worldwide.

o Medicaid Spending/Children's Health Team

Chris Jennings' group (HHS, Treasury, Labor, OMB, DPC, NEC) will begin meeting tomorrow to explore options for using the Federal government's share of recovered Medicaid funds for health care investments. This is an effort we had already planned to undertake to evaluate Hatch-Kennedy or similar legislation.

Outreach

Over the next two weeks, we will reach out to public health organizations and individuals and to members of Congress. Key public health contacts include: Action on Smoking and Health; American Cancer Society; American Heart Association; American Medical Association; American Academy of Pediatrics; American Public Health Association; Americans for Nonsmokers' Rights; National Center for Tobacco-Free Kids; Dr. Kessler; and Dr. Koop. We will also meet with other affected parties (states, farmers, small businesses) as appropriate.

Schedule

We have planned the following schedule, but note that adherence to this timetable is highly dependent on agency cooperation.

June 12:	Teams begin meeting.
June 18:	Teams report back with initial findings and outstanding issues.
Week of June 16:	White House and HHS host meetings with public health groups.
Week of June 23:	Develop options for outstanding issues; hold principals meeting.
June 27:	Send memo to the President.

Mike Moore told us today that the parties to the negotiations will meet Monday and try to reach agreement by mid-week.

MEMORANDUM

TO: Bruce and Elena

FROM: Chris

RE: **TOBACCO REVENUE MEETING TODAY AT 1PM**

cc: Elizabeth

DATE: June 12

At 1pm, there will be a meeting to discuss (a) the legalities of how the Federal government can take a share of the tobacco settlement; (b) possible uses of the money. Representatives from HHS, Labor, Treasury, OMB, NEC, DPC and the Vice President's Office will be in attendance.

Preliminary estimates suggest that the annual amount of the settlement related to Medicaid will be about $8 billion. Since the Federal government now pays 57 percent of Medicaid costs, on average, that means about $4.5 billion per year (the money will increase / phase in over time).

I have asked HHS to be primarily responsible for the substance of the discussion. Their lawyer will discuss the legal issues. Then, one of the policy people will suggest some general options for the use of the funds. It is assumed, in these discussions, that we will pass the $16 billion children's health initiative and this money will either supplement it or be used for something different. Examples of ideas include: expanding Medicaid for kids and using the $16 billion for grants for middle-income children; extending Medicaid for low-income seniors; funding public hospitals and clinics; and launching major research initiatives.

The meeting is more idea generating than decision making.

Please call with questions.

Monday 3:00 mtg

1) and Ogden?
OSTP - Jenny -
Leg

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
~~Assistant to the President for Domestic Policy~~
Bruce Lindsey
Rahm Emanuel

SUBJECT: Tobacco Settlement Review Process

~~This memo proposes~~ a process ~~for~~ evaluating the ~~expected~~ tobacco settlement ~~and for~~ seeking input from the public health community, ~~[and others?] on the agreement.~~ Our goal ~~would~~ is ~~be~~ to prepare ~~a~~ memo ~~to~~ the President ~~[by what date?]~~ that (1) defines the public health and public interest objectives of a global settlement; (2) ~~assesses~~ the settlement's strengths and weaknesses against those objectives **[and proposes modifications]** and (3) ~~reports~~ positions of the public health community **[and other affected ~~groups?~~]**;

- Start with the right document
- Make the document publicly available

Interagency Review

~~I suggest three~~ interagency ~~workgroups~~ -- ~~one to~~ examine the public health and liability issues; ~~(this group would do the bulk of the analytic work)~~, ~~a second to~~ review how to spend recovered Medicaid revenues ~~(we would assign to Chris Jennings existing health care team)~~; ~~and a third to consider international tobacco control issues.~~ ~~Each of~~ these ~~groups~~ will ~~answer the following:~~

~~What is the right~~ public health and public interest goal?;
~~What happens with no settlement?~~
~~What happens under the proposed settlement?~~
~~What~~ changes ~~would~~ we ~~want~~ in any global settlement?.

Public Health and Liability Working Group:

Participants: ~~HHS;~~ DoJ, Treasury, USDA, DoL, OMB
White House Offices (DPC, ~~OMB~~, OVP, Counsel, Leg. Affairs, Intergovernmental, Public Liaison) NEC OSTP

Issues:
1. FDA regulation of product, access, and labeling
2. Advertising restrictions / Public Education
3. Environmental Tobacco Smoke
4. Smoking Cessation
5. Farmers
6. Tobacco Industry Accountability and Oversight
7. Liability and Litigation
8. ~~Legislative feasibility~~ ~~Legal and legislative issues of enactment and~~ Drafting and enforcement issues in codifying a potential agmt.

Medicaid Spending/Children's Health Working Group: Chris J. will meet tomorrow with X (Led by Chris J) OMB

Participants: DPC/NEC Health Care Working Group ~~(Chris Jennings Chairs)~~

Issues: 1. Spending Priorities options
2. Possible arrangements with states

International ~~Issues~~ Subgroup

Participants: HHS, USTR, State, Commerce, NEC, NSC, DPC (~~Who Chairs?~~)

Issues: 1. U.S. leadership and responsibility in addressing growth of smoking worldwide.

Outreach

- Start with public health groups -- specifically, subgroups established by Koop/Kessler (youth smokers; adult smokers; environmental tobacco smoke; economic/industry issues; regulation of nicotine).
  - Meet with groups to hear their assessment of the critical issues before June 18.
  - Maintain the integrity of the Koop/Kessler process (don't ask for position prior to June 30).

member of Congress

- Second round of outreach to ~~X~~ state Attorneys general, governors, farmers, small businessmen, once our position is firmer.

Schedule

Meet Thursday, June 12, all groups to brief on process, assign tasks.

This depends on cooperation of the agency

June 12: Groups begin work
June 16-17: Meet with public health groups
June 19: Workgroups report back with initial findings and outstanding issues.
Week of June 23; develop options for outstanding issues; hold principals meeting;
Week of June 30: Final Consultation with public health community; consultation with other affected groups.
July.. Memo to the President.

— Meeting tomorrow — can Laura Set up.

Laura Emmett 06/11/97 02:47:47 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP

cc:
Subject: Tobacco Mtg.

---------- Forwarded by Laura Emmett/WHO/EOP on 06/11/97 02:50 PM ----------

Laura Emmett 06/02/97 03:32:09 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP

cc:
Subject: Tobacco Mtg.

---------- Forwarded by Laura Emmett/WHO/EOP on 06/02/97 03:34 PM ----------

Laura Emmett 06/02/97 11:33:18 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Tobacco Mtg.

We are setting up a meeting on tobacco strategy for this week. The meeting will take place Thursday June 5, at 1:00 in room 211. Please let me know if this does not work.

Attendees
Elena Kagan
Elizabeth Drye
Rahm Emanuel
Bruce Lindsey
Barbara Woolley
Anne McGuire
Dan Tate

Tracey Thornton
Andy Hyman- HHS
Bill Corr- HHS
Kevin Thurm-HHS
Harriet Rabb- HHS
Mitch Zeller- FDA
Jerry Mande- FDA
Bill Schultz- FDA
Jim O'Hara- FDA
George Phillips- DOJ

Message Sent To:

Michelle Crisci/WHO/EOP
Jennifer D. Dudley/WHO/EOP
Barbara D. Woolley/WHO/EOP
Anne E. McGuire/WHO/EOP
Daniel C. Tate/WHO/EOP
Tracey E. Thornton/WHO/EOP