

NLWJC - Kagan

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Tobacco-Settlement: General [1]

NATIONAL
GOVERNORS'
ASSOCIATION



News Release

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FYI for
Distribution

from Mickey
Barra

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FOR IMMEDIATE RELEASE

March 31, 1998

Contact: Becky Fleischauer 202/624-5364

40 GOVERNORS JOIN FORCES TO PRESS FOR A FEDERAL/STATE PARTNERSHIP IN TOBACCO LEGISLATION—*“The Question of Whether We Build on the Leadership of the States Hangs in the Balance”*

Washington D.C.— The nation’s governors joined forces today to urge the Senate Commerce Committee to recognize the critical role the states will play in achieving the goals of any tobacco legislation passed this year. “The question of whether we build on the leadership of the states in propelling this issue to center stage hangs in the balance of Washington politics,” said NGA Chairman Ohio Gov. George V. Voinovich and Vice Chairman Delaware Gov. Thomas R. Carper. “The success of this legislation depends on a full federal/state partnership.”

“Because the state lawsuits made a national settlement possible, states must be full partners in drafting settlement legislation,” said the 40-governor letter sent to Senate Commerce Committee Chairman John McCain (R-Ariz.) and Ranking Member Sen. Ernest F. Hollings (D-S.C.) today. “The ultimate success of a nationwide effort to reduce youth smoking will depend on state implementation, therefore states must be involved in designing programs that will work.”

Governors are committed to reducing youth smoking and restricting underage access to tobacco products and believe it will take the creative energy of each state to address the unique challenges states face in helping children grow up free from the temptations of tobacco. The letter urges Commerce Committee members to recognize that federal legislation should consider these differences and give states the flexibility necessary to succeed.

“Congress and the administration have an unprecedented opportunity to help secure a brighter future for today’s youth. The surest way for tobacco legislation to fail is for Congress and the administration to design a federal solution that ignores state needs and experiences. A top-down directive from Washington won’t get the job done,” said Govs. Voinovich and Carper.

The letter also noted that without the state leadership and years of effort that went into initiating state lawsuits, the nation wouldn’t be where we are today—on the verge of passing historic tobacco settlement legislation. States initiated the first lawsuits in 1994 to reduce youth smoking, secure public disclosure of tobacco documents, and recover state health care costs, among other goals.

In order to ensure that states receive a fair share of any national settlement, the governors expressed their support for a number of provisions in the Chaffee, Graham, Harkin bill introduced today. Specifically, the governors support elements of the bill that preclude the federal government from recouping funds through the Medicaid program, guarantee that states receive an amount similar to that negotiated by the state attorneys general in the original agreement, and allow states to use a portion of the settlement funds to prevent youth smoking and to improve the health, education, and welfare of our citizens.

“After bearing all of the risk initiating the suits and all of the expense of years of arduous negotiations and litigation necessary to develop these lawsuits, it is only reasonable and sensible that the funds made available to settle state suits should go to the states,” said Govs. Voinovich and Carper.

Forty-one states have filed suits against the tobacco industry. Florida, Mississippi, and Texas have declared victory in their lawsuits, and the Minnesota trial is underway. Whether a settlement is state-specific or part of a national agreement, the federal government is not entitled to take away from the states any of the funds negotiated on their behalf as a result of state lawsuits. Any efforts by the federal government to seek to recoup federal costs from these lawsuits must be distinct and separate.

—Letter attached—

MAR 31 '98 12:20PM NAT.

NATIONAL GOVERNORS ASSOCIATION

George A. Voinovich
Governor of Ohio
Chairman

Thomas R. Carver
Governor of Delaware
Vice Chairman

Kenneth S. Spillane
Executive Director

Hall of the States
444 North Capitol Street
Washington, DC 20541
Telephone 202-624-5313



March 30, 1998

The Honorable John McCain, Chair
Senate Commerce, Science, and Transportation Committee
241 Russell Senate Office Building
Washington, DC 20510

Dear Senator McCain:

The Senate Commerce, Science, and Transportation Committee will soon begin to mark up one of the most important bills Congress will consider this year -- comprehensive tobacco settlement legislation. Given the vital role you and your committee will play in determining the fate of tobacco legislation in the Senate, the nation's Governors want to make you aware of the states' priorities and concerns as you prepare to move forward. It is critical that Governors and your committee work together closely and engage in an ongoing dialogue as mark up begins and the bill moves through the legislative process.

The states' interest in taking action to reduce youth smoking is longstanding. The national debate over tobacco settlement legislation was made possible by years of state effort and leadership. In 1994 the first broad lawsuits were filed by states against the tobacco industry based on claims including consumer protection, fraud, racketeering, antitrust violations, and health care costs. Since that time, forty-one states and territories have filed their own lawsuits to reduce youth smoking, secure public disclosure of tobacco documents, and recoup health care costs, among other goals. Medicaid represents only a portion of the state suits, in some states only a small portion.

Because the state lawsuits made a national settlement possible, the states must be full partners in drafting settlement legislation. The ultimate success of a nationwide effort to reduce youth smoking will depend on state implementation, so states must be involved in designing programs that will work.

Programmatic reforms will be at the center of any tobacco settlement. The Governors are committed to reducing youth smoking and restricting young people's access to tobacco products. We recognize that Congress will likely adopt the Food and Drug Administration's (FDA) recommendations related to nationwide access standards, but the states should be given flexibility to design and implement the most effective means of enforcing those standards. States must be involved in setting targets so that these goals are not arbitrary and can be achieved through aggressive implementation of the reforms set forth in the bill. Retail licensing should remain a state responsibility, and penalties for violations should be state designed. Efforts to reduce exposure to environmental smoke should be undertaken at the state and local levels. Any bill under consideration must address the needs of tobacco farmers and their communities and the need for a tobacco program.

In addition to these programmatic priorities, the distribution of settlement funds will also be an issue of considerable importance to the nation's Governors. The Governors strongly believe that settlement

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funds fall into two basic categories: direct payments to states and federal settlement funds. If legislation is intended to resolve the state lawsuits against the industry, a significant portion of any tobacco settlement funds must go to the states. We are not arguing that states should receive all of the funds flowing from national legislation, but they should receive a portion of the total that reflects state leadership in bringing about a settlement. This state portion must be a distinct and protected core of the final package, and states should not be restricted in the use of these funds. The federal government should receive a separate pool of funds to finance its prioritized investments.

The Governors strongly oppose federal recoupment of state tobacco settlement funds. However, some in Congress and the administration consider a portion of the state share of settlement funds to be vulnerable to federal recoupment as Medicaid overpayments. To resolve this issue and keep the disputed funds in the states, the Governors would be willing to agree to use that percentage of state settlement funds potentially vulnerable to recoupment for health, education, and welfare programs.

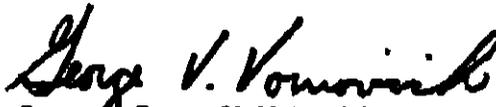
Legislation currently being developed by Senators John Chafee (R-R.I.), Bob Graham (D-Fla.), and Tom Harkin (D-Iowa) includes a state payment section that successfully addresses Governors' priorities related to settlement funds. Their bill includes a number of important elements. First, the federal government is precluded from recouping funds through the Medicaid program. Second, states are guaranteed an amount similar to that negotiated by the state attorneys general in the original agreement. Third, states will receive both an unrestricted pool of funds and a separate, directed pool to be used to prevent youth smoking and to improve the health, education, and welfare of our citizens. The Governors support the state payment mechanism set forth in the Chafee/Graham/Harkin legislation and encourage you to incorporate it into your bill.

Absent passage of comprehensive legislation settling state lawsuits, it will be critical to the states that a more targeted tobacco package include clarification that funds negotiated by the states to resolve their individual lawsuits are not vulnerable to seizure by the federal government. State lawsuits were developed and pursued without federal assistance. The Governors will strongly oppose efforts by the federal government to stretch current law to take from the states what could amount to more than half of some states' settlement awards.

An analysis of how federal legislation addresses our programmatic and financial concerns will help Governors determine whether we counsel our attorneys general to sign consent decrees resolving state lawsuits or whether instead states would be better served by pursuing their individual lawsuits against the industry. National legislation must not reduce states to afterthoughts in the process we initiated.

We appreciate your consideration of our perspective. If we can provide you with additional information, please contact the National Governors' Association.

Sincerely,


Governor George V. Voinovich
Chairman


Governor Thomas R. Carper
Vice Chairman

THE WHITE HOUSE
WASHINGTON

September 15, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Tobacco Rollout Plan

This memo describes the rollout plan for our tobacco announcement. Our goal is to build momentum and support for the enactment of comprehensive tobacco legislation within the next year.

Notifying Key Players

Prior to the announcement, we will inform key players about what the President plans to say on Wednesday. We are working with OPL, Legislative Affairs, Intergovernmental Affairs, and HHS toward ensuring that key members of Congress, attorneys general, governors, and leaders of the public health community are prepared to validate the President's position.

Donna and I will meet with the House and Senate Democratic Tobacco Task Forces late in the day on Tuesday. We will offer to meet with the Republican leadership. White House and HHS legislative affairs will contact relevant committee chairs and ranking members. I will call Governors Hunt, Patton, and Chiles and David Kessler, C. Everett Koop, and Matt Myers. Bruce Lindsey will call the attorneys general. OPL and DPC will call the more than 50 participants of our public outreach meetings.

Event and Communications

There will be considerable press interest in our announcement. We should take advantage of the heightened interest to get out our message, shape the debate, and build momentum for enactment of comprehensive tobacco legislation.

Mike McCurry, Rahm, and I have developed a plan to give advance details of the President's proposal to the major papers for Wednesday morning. With so many Members of Congress being briefed tomorrow, we don't think the story would hold anyway.

To get the most out of the event itself, we should do a Rose Garden event where we can surround the President with leaders from the public health community, the attorneys general, and members of Congress. From the public health community, we expect officials of the American Cancer Society, the American Heart Association, and the American Medical Association, as well

as David Kessler, Matt Myers, and possibly C. Everett Koop. From the attorneys general, we expect Mike Moore, Christine Gregoire, Grant Woods, and possibly Bob Butterworth and Scott Harshberger. From Congress, we hope to attract members and leadership from both parties. The audience of 100-150 will be a mix of public health experts who participated in our public outreach meetings, agency staff who participated in the interagency review, and individuals from a list given to us by the Campaign for Tobacco-Free Kids.

The event itself will be limited to remarks by the Vice-President and President. Donna, Dan Glickman, and I will join the President, Vice-President, and validators on stage. Donna and I will lead Mike McCurry's afternoon briefing.

We will provide a short handout to the press describing the President's approach to tobacco legislation, and we will prepare Q&As for the press office and others.

Follow-up

In addition to the typical follow-up briefings for interested groups, we will develop a detailed plan of actions for the remainder of 1997 to maintain interest in and build momentum for enactment of comprehensive tobacco legislation next year. We will work with the Vice-President and his staff to establish a visible leadership role for him. At the same time, we will develop a detailed plan for working with Congress to enact legislation. The President will announce Wednesday that he will invite Congressional leaders to the White House in the coming weeks to develop a bipartisan process to enact tobacco legislation.

Name	Date
<i>Marlaine</i>	<i>4/5/2000</i>

counsel

President Clinton's Plan for Comprehensive Tobacco Legislation to Protect America's Children

Today, President Clinton challenged Congress to pass sweeping tobacco legislation to reduce teen tobacco use significantly. The President announced that he will invite Congressional leaders in both parties to the White House in the coming weeks to launch a bipartisan effort to enact federal tobacco legislation. That legislation will build on the extraordinary efforts of the nation's attorneys general, who helped create an historic opportunity for progress in reducing smoking, especially by youth.

In August 1996, the Clinton Administration announced a landmark rule by the Food and Drug Administration to protect children from the harm caused by tobacco products, which was upheld by a federal judge in North Carolina earlier this year. Those victories for the public health, along with the aggressive efforts of the attorneys general and leaders of the public health community, drove the tobacco companies to the bargaining table and extracted concessions that would have been unimaginable just a short time ago.

Since a proposed national settlement was announced June 20, the Administration -- led by Vice President Gore, Secretary of Health and Human Services Donna Shalala, and Domestic Policy Advisor Bruce Reed -- has been working with the public health community, the attorneys general, members of Congress, tobacco farmers, and others to develop a comprehensive tobacco policy.

Today, the President announced five key elements that must be at the heart of any national tobacco legislation:

1. A Comprehensive Plan to Reduce Teen Smoking, Including Tough Penalties If Targets Are Not Met. Every day, 3,000 young people start smoking regularly, and 1,000 of them will die early as a result. The central goal of tobacco legislation must be a comprehensive, nationwide effort to reduce teen smoking. The Administration is calling for:

- **Tough Penalties and Price Increases to Reduce Teen Smoking:** The Administration believes tobacco legislation must include stiff penalties that give the tobacco industry the strongest possible incentive to stop targeting kids. Legislation should set ambitious targets to cut teen smoking by 30% in 5 years, 50% in 7 years, and 60% in 10 years, and impose severe financial penalties that hold tobacco companies accountable to meet those targets. The Administration supports penalties that are non-deductible, uncapped, and escalating -- so that the penalties get stiffer and the price goes up the more that companies miss the targets. Reducing youth smoking is the Administration's bottom line, and now it must be the industry's bottom line.

One of the surest ways to reduce youth smoking is to increase the price of cigarettes. By some estimates, a 10% increase in cigarette prices will lead to a 7% drop in youth smoking. **Today, the President called for a combination of industry payments and penalties to increase the price of cigarettes by up to \$1.50 a pack over the next decade as necessary to meet the youth smoking reduction targets.**

- **A Public Education and Counter Advertising Campaign:** To succeed in reducing youth smoking, legislation must provide for a nationwide effort to deglamorize tobacco, warn young people of its addictive nature and deadly consequences, and help parents discourage their children from taking up the habit. Legislation should provide for a public education and counter advertising campaign, as well as state and local prevention efforts. The Administration also supports stronger, more visible warning labels on tobacco products.
- **Expanded Efforts to Restrict Access and Limit Appeal:** The current FDA rule includes significant measures to reduce youth access to tobacco products (such as requiring retailers to check photo identification of anyone under 27) and to limit the advertising of tobacco to young people (such as restricting advertising near school buildings). The Administration supports legislation codifying these measures, imposing even stronger restrictions on youth access and advertising consistent with the Constitution, and establishing an effective retail licensing scheme with tough penalties.

2. Full Authority for FDA to Regulate Tobacco Products. In 1996, the Administration took the historic step of asserting FDA jurisdiction over tobacco products. Since that time, the Administration has said it would support federal legislation explicitly affirming the FDA's authority to regulate the manufacture, marketing, and sale of tobacco products. Under such legislation, the FDA's authority over tobacco products must be as effective as its authority over other drugs and devices, and must be sufficiently flexible to meet changing circumstances. The legislation should not impose any obligation on the FDA to make specific findings about such speculative matters as the creation of contraband markets; nor should it impose any special procedural hurdles or requirements, such as enhanced standards of proof or unusual evidentiary formalities.

3. Changes in the Way the Tobacco Industry Does Business. Federal tobacco legislation must include measures to expose the industry's past misconduct, especially its efforts to market products to children, and to change the way the industry does business.

- **No Marketing to Children:** Commitments by the industry -- such as agreements to limit advertising to children -- can serve to recognize the need for increased

corporate responsibility. Today, the President reiterated his call to the tobacco industry to stop marketing and promoting tobacco to children.

- **Document Disclosure:** To ensure that patterns of corporate malfeasance are disclosed and effectively checked in the future, tobacco legislation must provide for broad disclosure of industry documents, especially those containing scientific or other health information or relating to the industry's attempts to market tobacco to children. This legislation should respect essential principles of attorney-client privilege. But the legislation should establish effective mechanisms to turn over to the public all non-privileged documents, including documents the industry has inappropriately claimed to be privileged, as well as to disclose scientific and health-related information in even privileged documents.
- **Corporate Compliance:** Tobacco companies should set up comprehensive corporate compliance programs that will reinforce the real economic incentives provided by the youth smoking penalties to discourage companies from marketing to children. The legislation should establish oversight mechanisms to investigate and monitor corporate compliance and to make recommendations to Congress on appropriate future legislation.

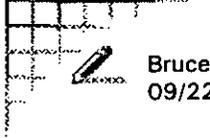
4. Progress Toward Other Public Health Goals. Federal tobacco legislation provides an opportunity not only to reduce youth smoking, but to meet other public health goals: the reduction of environmental (second-hand) tobacco smoke, the expansion of smoking cessation programs, the strengthening of international efforts to control tobacco, and the provision of funds for health research and other health objectives.

- **Second-Hand Smoke:** The best scientific studies show that restrictions on second-hand smoke reduce the risk of death and injury to non-smokers, including the hundreds of thousands of children with asthma and other respiratory illness, and lead many smokers to quit the habit. Federal tobacco legislation should include provisions to restrict smoking in workplaces and other public facilities of the kind found in H.R. 3434, as well as in the President's recent Executive Order on tobacco smoke in federal facilities.
- **Smoking Cessation Programs:** Data suggests that some 70% of smokers want to quit, but fewer than 3% each year successfully do so. Legislation should help enable smoking cessation services to reach and assist the millions of smokers who want to break their addiction to tobacco products.
- **International Leadership:** According to the World Health Organization (WHO), tobacco use now causes 3 million deaths a year worldwide; unless checked, that number will rise to 10 million by 2025, with 70% of annual deaths

occurring in developing countries. Legislation should strengthen global and bilateral efforts to reduce smoking by providing assistance to international institutions.

- **Resources for Health Research and Other Health Care Objectives:** The Administration believes that the primary objective of tobacco legislation is to reduce youth smoking, not to raise money. But tobacco legislation also should take into account the health costs associated with smoking and the resulting need for public health investments. Legislation should generate sufficient resources to establish a health research fund and contribute significantly to other important health objectives. In addition, Congress should repeal the provision giving the tobacco industry a \$50 billion credit.

5. Protection for Tobacco Farmers and Their Communities. The President made clear today that any tobacco legislation must protect tobacco farmers and their communities. Most tobacco farmers live and work on small family farms; in many cases, their families have been growing tobacco for generations. In some states, entire communities rely on income from the tobacco crop. The Administration is committed to working with members of Congress in both parties to ensure that we protect the financial well-being of tobacco farmers, their families, and their communities.



Bruce N. Reed
09/22/97 06:14:11 PM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP
cc: Elena Kagan/OPD/EOP
Subject: tobacco process

We need to write up a tobacco strategy/process memo for EB et al. Then we need to have zillions of mtgs on process, strategy, etc. Here are a few thoughts:

GOAL

Bipartisan bill by year-end

MEETINGS

1. Weekly Tobacco Strategy/Communications Meeting -- with key people from WH and agencies. DPC (EK, BR, TF, CJ, Lambrew, JRM), VP (Gips/Toby), OPL (Wooley), IGA (Emily), Toiv, Leg Affairs (Tate, Carey), Lindsey (optional), NEC, OMB, HHS (Tarplin, Skolfield, O'Hara), Treasury (Gruber), USDA, DOJ (Phillips). Tuesday is Tom's preference.
2. Weekly conference call with Mike Moore's group (Moore, Scruggs, Coale)
3. Weekly conference call/meeting with public health group (K-K, Myers/Novelli, AHA, AMA, ACS) -- include HHS, VP

LEGISLATIVE OUTREACH

1. Reed/Shalala rounds to key members on Hill over next 2 wks
2. Plan WH mtg with Leadership (schedule for early October)
-- Hilley/Bowles outreach to Lott/Gingrich
3. Continue policy development

COMMUNICATIONS

1. Schedule of events for rest of 97

POTUS Q&A
Tobacco

1. Does what you've said here today mean the tobacco deal is dead? (Hasn't your Administration squandered this opportunity?)

Not at all. We've put forward a sound, reasonable plan to cut teen smoking. I think people in both parties can support it. We're determined to work with Congress to get it right but get it done. The VP and I will work relentlessly to make this happen.

2. Are you walking away from the settlement? (Didn't you put your friends out on a limb and saw them off?)

No. We're building on the settlement, and on the hard work the attorneys general did to get us to this point. The settlement creates an historic opportunity to enact comprehensive tobacco legislation with support from across the board. (Mention Moore, Woods, Gregoire)

3. After three months, why isn't your plan more specific?

We've been very clear on our priorities: We want to focus first and foremost on cutting teen smoking, and enact tough penalties that force the tobacco industry to take responsibility to do so. We want a national counter advertising campaign to warn young people of the dangers of smoking. We want to preserve FDA authority over tobacco products. We want to protect all Americans from the dangers of secondhand smoke. And we want to make sure that farmers who've been raising tobacco for generations don't see their livelihoods washed away. We're determined to work with Congress in a bipartisan fashion, as we did in balancing the budget, to reach agreement on legislation that reflects these goals.

4. How active will you be in pressing for tobacco legislation?

Reducing teen smoking has been a priority of mine for years now. I'll be very active -- and the Vice President will lead our efforts to build bipartisan support around the country for this plan. I want to approach this in the same bipartisan spirit that enabled us to balance the budget. We're determined to work with Congress to get it right and get it done.

THE WHITE HOUSE
WASHINGTON

September 16, 1997

TOBACCO ANNOUNCEMENT

DATE: September 17, 1997
LOCATION: Oval Office
BRIEFING TIME: 10:00 am - 10:30 am
EVENT TIME: 10:30 am - 10:55 am
FROM: Bruce Reed

I. PURPOSE

To launch the Administration's plan for comprehensive tobacco legislation to reduce youth smoking.

II. BACKGROUND

You will challenge Congress to enact federal tobacco legislation to reduce teen smoking and announce five key elements that must be included in any national legislation. You will also announce that you will invite Congressional leaders to the White House to work on this issue in the coming weeks. This is an opportunity to build on the FDA rule and the efforts of attorneys general to take further steps to curb youth smoking.

In your remarks, you will call for national tobacco legislation that includes the following:

1. **A comprehensive plan to reduce teen smoking**, including tough penalties if targets are not met, a public education campaign, and expanded efforts to prevent youth access to tobacco products. Legislation should set ambitious targets to reduce teen smoking by 30% in 5 years, 50% in seven years, and 60% in 10 years.
2. **Full authority for the FDA to regulate tobacco products.**
3. **Changes in the way the tobacco industry does business**, including: no marketing to children, increase document disclosure, and mandatory corporate compliance programs.
4. **Progress toward meeting other public health goals**, such as: the reduction of second-hand smoke, the expansion of smoking cessation programs, the strengthening of international efforts to control tobacco, and the provision of funds for medical research and other health objectives.
5. **Protection for tobacco farmers and their communities.**

The attached document, which will be released to the press, provides more specifics.

Since the announcement of a proposed national settlement on June 20, the Administration has consulted with the public health community, the attorneys general, members of Congress, tobacco farmers, and others to develop a comprehensive tobacco policy. At this event, you will be joined by several key representatives from the public health community and attorneys general to demonstrate unified support for your efforts.

III. PARTICIPANTS

Briefing Participants:

The Vice President
Secretary Shalala
Erskine Bowles
Bruce Reed
Elena Kagan
Don Gips

Event Participants:

The Vice President
Secretary Shalala
Secretary Glickman
Bruce Reed
Dr. C. Everett Koop
Dr. David Kessler
Four Members of Congress (as yet unknown)
Attorney General Michael "Mike" Moore (D-Mississippi)
Attorney General Grant Woods (R-Arizona)
Attorney General Christine Gregoire (D-Washington)
Attorney General Robert Butterworth (D-Florida)
Attorney General Skip Humphrey (D-Minnesota)
Dr. Randolph Smoak, Vice Chair of the Board, American Medical Association
Dr. John Seffrin, CEO, American Cancer Society
Dudley Hafner, Executive Vice President, American Heart Association
Matt Myers, Executive Vice President and General Counsel, Campaign for Tobacco Free

Kids

IV. PRESS PLAN

Pool Press.

V. SEQUENCE OF EVENTS

- You will enter the Oval Office accompanied by the Vice President. (Other guests will be pre-positioned.)
- The Vice President will make welcoming remarks and introduce you.
- You will make remarks and then take questions from the pool.

VI. REMARKS

Remarks provided by Speechwriting.

President Clinton's Plan for Comprehensive Tobacco Legislation to Protect America's Children

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In August 1996, the Clinton Administration announced a landmark rule by the Food and Drug Administration to protect children from the harm caused by tobacco products, which was upheld by a federal judge in North Carolina earlier this year. Those victories for the public health, along with the aggressive efforts of the attorneys general and leaders of the public health community, drove the tobacco companies to the bargaining table and extracted concessions that would have been unimaginable just a short time ago.

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- **Corporate Compliance:** Tobacco companies should set up comprehensive corporate compliance programs that will reinforce the real economic incentives provided by the youth smoking penalties to discourage companies from marketing to children. The legislation should establish oversight mechanisms to investigate and monitor corporate compliance and to make recommendations to Congress on appropriate future legislation.

4. Progress Toward Other Public Health Goals. Federal tobacco legislation provides an opportunity not only to reduce youth smoking, but to meet other public health goals: the reduction of environmental (second-hand) tobacco smoke, the expansion of smoking cessation programs, the strengthening of international efforts to control tobacco, and the provision of funds for health research and other health objectives.

- **Second-Hand Smoke:** The best scientific studies show that restrictions on second-hand smoke reduce the risk of death and injury to non-smokers, including the hundreds of thousands of children with asthma and other respiratory illness, and lead many smokers to quit the habit. Federal tobacco legislation should include provisions to restrict smoking in workplaces and other public facilities of the kind found in H.R. 3434, as well as in the President's recent Executive Order on tobacco smoke in federal facilities.
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occurring in developing countries. Legislation should strengthen global and bilateral efforts to reduce smoking by providing assistance to international institutions.

- **Resources for Health Research and Other Health Care Objectives:** The Administration believes that the primary objective of tobacco legislation is to reduce youth smoking, not to raise money. But tobacco legislation also should take into account the health costs associated with smoking and the resulting need for public health investments. Legislation should generate sufficient resources to establish a health research fund and contribute significantly to other important health objectives. In addition, Congress should repeal the provision giving the tobacco industry a \$50 billion credit.

5. Protection for Tobacco Farmers and Their Communities. The President made clear today that any tobacco legislation must protect tobacco farmers and their communities. Most tobacco farmers live and work on small family farms; in many cases, their families have been growing tobacco for generations. In some states, entire communities rely on income from the tobacco crop. The Administration is committed to working with members of Congress in both parties to ensure that we protect the financial well-being of tobacco farmers, their families, and their communities.

President Clinton's Plan for Comprehensive Tobacco Legislation to Protect America's Children

Today, President Clinton challenged Congress to pass sweeping tobacco legislation to reduce teen tobacco use significantly. The President announced that he will invite Congressional leaders in both parties to the White House in the coming weeks to launch a bipartisan effort to enact federal tobacco legislation. That legislation will build on the extraordinary efforts of the nation's attorneys general, who helped create an historic opportunity for progress in reducing smoking, especially by youth.

In August 1996, the Clinton Administration announced a landmark rule by the Food and Drug Administration to protect children from the harm caused by tobacco products, which was upheld by a federal judge in North Carolina earlier this year. Those victories for the public health, along with the aggressive efforts of the attorneys general and leaders of the public health community, drove the tobacco companies to the bargaining table and extracted concessions that would have been unimaginable just a short time ago.

Since a proposed national settlement was announced June 20, the Administration -- led by Vice President Gore, Secretary of Health and Human Services Donna Shalala, and Domestic Policy Advisor Bruce Reed -- has been working with the public health community, the attorneys general, members of Congress, tobacco farmers, and others to develop a comprehensive tobacco policy.

Today, the President announced five key elements that must be at the heart of any national tobacco legislation:

1. A Comprehensive Plan to Reduce Teen Smoking, Including Tough Penalties If Targets Are Not Met. Every day, 3,000 young people start smoking regularly, and 1,000 of them will die early as a result. The central goal of tobacco legislation must be a comprehensive, nationwide effort to reduce teen smoking. The Administration is calling for:

- **Tough Penalties and Price Increases to Reduce Teen Smoking:** The Administration believes tobacco legislation must include stiff penalties that give the tobacco industry the strongest possible incentive to stop targeting kids. Legislation should set ambitious targets to cut teen smoking by 30% in 5 years, 50% in 7 years, and 60% in 10 years, and impose severe financial penalties that hold tobacco companies accountable to meet those targets. The Administration supports penalties that are non-deductible, uncapped, and escalating -- so that the penalties get stiffer and the price goes up the more that companies miss the targets. Reducing youth smoking is the Administration's bottom line, and now it must be the industry's bottom line.

One of the surest ways to reduce youth smoking is to increase the price of cigarettes. By some estimates, a 10% increase in cigarette prices will lead to a 7% drop in youth smoking. Today, the President called for a combination of industry payments and penalties to increase the price of cigarettes by up to \$1.50 a pack over the next decade as necessary to meet the youth smoking reduction targets.

- **A Public Education and Counter Advertising Campaign:** To succeed in reducing youth smoking, legislation must provide for a nationwide effort to deglamorize tobacco, warn young people of its addictive nature and deadly consequences, and help parents discourage their children from taking up the habit. Legislation should provide for a public education and counter advertising campaign, as well as state and local prevention efforts. The Administration also supports stronger, more visible warning labels on tobacco products.
- **Expanded Efforts to Restrict Access and Limit Appeal:** The current FDA rule includes significant measures to reduce youth access to tobacco products (such as requiring retailers to check photo identification of anyone under 27) and to limit the advertising of tobacco to young people (such as restricting advertising near school buildings). The Administration supports legislation codifying these measures, imposing even stronger restrictions on youth access and advertising consistent with the Constitution, and establishing an effective retail licensing scheme with tough penalties.

2. Full Authority for FDA to Regulate Tobacco Products. In 1996, the Administration took the historic step of asserting FDA jurisdiction over tobacco products. Since that time, the Administration has said it would support federal legislation explicitly affirming the FDA's authority to regulate the manufacture, marketing, and sale of tobacco products. Under such legislation, the FDA's authority over tobacco products must be as effective as its authority over other drugs and devices, and must be sufficiently flexible to meet changing circumstances. The legislation should not impose any obligation on the FDA to make specific findings about such speculative matters as the creation of contraband markets; nor should it impose any special procedural hurdles or requirements, such as enhanced standards of proof or unusual evidentiary formalities.

3. Changes in the Way the Tobacco Industry Does Business. Federal tobacco legislation must include measures to expose the industry's past misconduct, especially its efforts to market products to children, and to change the way the industry does business.

- **No Marketing to Children:** Commitments by the industry -- such as agreements to limit advertising to children -- can serve to recognize the need for increased

corporate responsibility. Today, the President reiterated his call to the tobacco industry to stop marketing and promoting tobacco to children.

- **Document Disclosure:** To ensure that patterns of corporate malfeasance are disclosed and effectively checked in the future, tobacco legislation must provide for broad disclosure of industry documents, especially those containing scientific or other health information or relating to the industry's attempts to market tobacco to children. This legislation should respect essential principles of attorney-client privilege. But the legislation should establish effective mechanisms to turn over to the public all non-privileged documents, including documents the industry has inappropriately claimed to be privileged, as well as to disclose scientific and health-related information in even privileged documents.
- **Corporate Compliance:** Tobacco companies should set up comprehensive corporate compliance programs that will reinforce the real economic incentives provided by the youth smoking penalties to discourage companies from marketing to children. The legislation should establish oversight mechanisms to investigate and monitor corporate compliance and to make recommendations to Congress on appropriate future legislation.

4. Progress Toward Other Public Health Goals. Federal tobacco legislation provides an opportunity not only to reduce youth smoking, but to meet other public health goals: the reduction of environmental (second-hand) tobacco smoke, the expansion of smoking cessation programs, the strengthening of international efforts to control tobacco, and the provision of funds for health research and other health objectives.

- **Second-Hand Smoke:** The best scientific studies show that restrictions on second-hand smoke reduce the risk of death and injury to non-smokers, including the hundreds of thousands of children with asthma and other respiratory illness, and lead many smokers to quit the habit. Federal tobacco legislation should include provisions to restrict smoking in workplaces and other public facilities of the kind found in H.R. 3434, as well as in the President's recent Executive Order on tobacco smoke in federal facilities.
- **Smoking Cessation Programs:** Data suggests that some 70% of smokers want to quit, but fewer than 3% each year successfully do so. Legislation should help enable smoking cessation services to reach and assist the millions of smokers who want to break their addiction to tobacco products.
- **International Leadership:** According to the World Health Organization (WHO), tobacco use now causes 3 million deaths a year worldwide; unless checked, that number will rise to 10 million by 2025, with 70% of annual deaths

occurring in developing countries. Legislation should strengthen global and bilateral efforts to reduce smoking by providing assistance to international institutions.

- **Resources for Health Research and Other Health Care Objectives:** The Administration believes that the primary objective of tobacco legislation is to reduce youth smoking, not to raise money. But tobacco legislation also should take into account the health costs associated with smoking and the resulting need for public health investments. Legislation should generate sufficient resources to establish a health research fund and contribute significantly to other important health objectives. In addition, Congress should repeal the provision giving the tobacco industry a \$50 billion credit.

5. Protection for Tobacco Farmers and Their Communities. The President made clear today that any tobacco legislation must protect tobacco farmers and their communities. Most tobacco farmers live and work on small family farms; in many cases, their families have been growing tobacco for generations. In some states, entire communities rely on income from the tobacco crop. The Administration is committed to working with members of Congress in both parties to ensure that we protect the financial well-being of tobacco farmers, their families, and their communities.

Questions and Answers on the Tobacco Settlement
September 17, 1997

Q: Is the Administration endorsing the settlement?

A: The Administration called for a legislative solution to the public health issue of tobacco and children in August 1995. The President said then that national legislation would be the best way to protect our children, and that is still the Administration's position. The settlement announced last June creates an historic opportunity to enact this legislation. The President's plan builds on the settlement by demanding:

- A comprehensive plan to reduce teen smoking, including tough penalties if targets are not met, a public education and counter advertising campaign, and expanded efforts to restrict the access of youth to tobacco products;
- Full authority for the FDA to regulate tobacco products;
- Changes in the way industry does business, including broad document disclosure;
- Progress toward other public health goals, including reduction of second-hand smoke, expansion of smoking cessation programs, strengthening of international efforts, and funding for health research and other health objectives; and
- Protection for tobacco farmers and their communities.

Q: Many believe that by not accepting the settlement, you will drive the tobacco companies away and kill any chances of legislation.

A: We want national legislation focused on curbing youth smoking, but we want it to be complete and we want it to be right. We are proposing the principles that we believe are necessary for tobacco legislation. What the industry thinks of those principles is not what should guide us.

Q: Why did it take you so long to comment on the settlement -- especially when you have provided so few specifics?

A: This is an extremely important and complex subject, and we wanted to make sure we got everything right. We have never intended to write legislation or to provide details of a legislative proposal. We will need to work closely with Congress on this issue. We think that providing principles is the best way to start what we hope will be a bipartisan process

to enact legislation.

Q: Is the White House to blame that there's no chance of getting national legislation through Congress this year?

A: No. The Republican Leadership has made clear for some time that it would not be ready to enact legislation this year. And we understand why not. This is a complicated issue. It needs to be done with great thought and care in order to get it right. But we have great hopes that the Administration and Congress can work together to enact bipartisan legislation in the next several months.

Q: What is the Administration doing to do to get Congress to pass national tobacco legislation?

A: The President will invite congressional leaders and key members to the White House in the coming weeks to launch a bipartisan effort to enact tobacco legislation. The President has also asked the Vice President to lead the effort to mobilize support around the nation for tobacco legislation.

Q: Why is the Administration proposing price increases of up to \$1.50 per pack?

A: We know that significant price increases will help reduce underage smoking -- some experts estimate that for each 10% increase, there is a 7% drop in youth smoking. Today the President called for a combination of industry payments and penalties to increase the price of cigarettes by up to \$1.50 as necessary to meet youth reduction targets. If companies meet the goals of reducing youth smoking, penalties will not be levied, and the price increases may be smaller. What is key is that the price go up as needed to meet the targets.

Q: How much of the \$1.50 will be collected in base payments and how much will be in the form of penalties for industry failure to meet youth smoking reduction targets?

A: We will work with Congress in addressing that issue. It may be that penalties will account for a much more significant portion of the total cost than in the initial settlement proposal.

Q: Why doesn't the Administration just propose an increased excise tax?

A: We're for increasing the tobacco excise tax. But we just fought a huge battle to increase the excise tax by a modest 15 cents -- only to have the tobacco industry insert a provision in the balanced budget agreement to recoup the money. We believe our proposal can more easily be achieved -- and that it will be just as effective in accomplishing our goal of reducing youth smoking.

Q: What should "FDA's full authority" consist of?

A: Full authority for FDA means no special restrictions on the agency's ability to regulate tobacco products. This means doing away with procedural and substantive obstacles -- like having to make a contraband finding -- that would have restricted the agency's ability to protect the public. And it means retaining the FDA's flexibility to adjust federal regulation in the future to respond to changes in the way the industry manufacturers, markets, or advertises its products.

Q: Do you want FDA to start eliminating nicotine from tobacco products?

A: No. The experts say that much more needs to be known, including information from the documents the industry has kept secret, before FDA can even consider regulating the nicotine content of tobacco products. Our point is simple -- we need a strong FDA, and we need to make sure FDA has all the information it needs so that it can properly evaluate issues like nicotine content.

Q: What is your position on the disclosure of tobacco industry documents?

A: This industry has hidden the truth from the American public for many decades. We must have broad disclosure of what the industry has known, but kept secret, about scientific and health issues and about marketing to children. Legislation should respect essential principles of attorney-client privilege. But the legislation should establish effective mechanisms to turn over to the public all non-privileged documents (including ones the industry has falsely claimed to be privileged) and disclose scientific and health information contained in even privileged documents.

Q: What are your views on the industry's demand for civil liability protection as part of any legislation?

A: We must have legislation that protects our children from the hazards of tobacco. The Administration will not support any bill that fails to do that. Any limits on liability are conditional on the legislation meeting the Administration's full set of demands.

Q: Aren't there sufficient restrictions on smoking in public places?

A: Increasing the protection for the nation's nonsmokers is a very high priority. Every day we learn more about the adverse effects of "environmental tobacco smoke," or ETS, particularly among youth. ETS causes about 3,000 lung cancer deaths each year in nonsmoking adults, has been linked to other health problems such as heart disease and SIDS, and causes numerous childhood respiratory illnesses. Reducing smoking in workplaces and other public places is one of the most important objectives of comprehensive tobacco legislation.

Q: What about farmers? What will you do to protect them?

A: The President made clear today that any tobacco legislation must protect tobacco farmers and their communities. Most tobacco farmers live and work on small family farms; in many cases, their families have been growing tobacco for generations. In some states, entire communities rely on income from the tobacco crop. The Administration is committed to working with members of Congress in both parties to ensure that we protect the financial well-being of tobacco farmers, their families, and their communities.

Q: What provisions will you make for the payment of legal fees to attorneys for the settling parties?

A: The settlement did not address this issue, and our proposal certainly will not. Our proposal is focused on reducing youth smoking. The resources we are asking for are the resources that will allow us to meet this objective and to meet other critical public health needs. What lawyers for any of the parties get is not our concern, nor will it ever be.

Q: What will happen if we fail to seize this opportunity?

A: If current trends continue and nothing is done to curtail tobacco use in America, we can expect an additional 25 million painful and premature deaths among currently living Americans, including five million of our children. On average, smokers who die from smoking-related diseases will lose an average 12 years of life, resulting in medical expenditures of \$50 billion per year.

Q: Why has tobacco become such an important issue to this Administration?

A: We've been working on this for two years now. Each day 3000 young people become regular smokers, replacing many of the adult smokers who have quit or died. As the 20th

century comes to a close, we need to "right our past wrongs" and bring to a close a century of neglect in dealing with the greatest preventable cause of death in our society. We need to protect our children from being seduced, and then addicted, and finally afflicted. We need to enter the 21st century with policies and programs in place which treat tobacco commensurate with the harm that it causes.

PRESIDENT CLINTON
FIGHTING YOUTH TOBACCO USE

President Clinton understands the danger tobacco use poses to the health of our children, and he has taken bold action on this pressing public health concern.

A RECORD OF ACHIEVEMENT

First-Ever Plan to Protect Our Children from Tobacco. On August 10, 1995, President Clinton announced executive action to protect our nation's young people from the dangers of tobacco by sharply restricting the advertising, promotion, distribution, and marketing of cigarettes to teenagers. The President authorized the Food and Drug Administration (FDA) to initiate a broad series of steps all designed to stop sales and marketing of cigarettes and smokeless tobacco to children.

Strong FDA Action. One year later, on August 23, 1996, the President's program was launched with the unveiling of the FDA final rule on tobacco and children. The FDA's actions were aimed at reducing the appeal of tobacco products to teenagers.

Cracking Down on Youth Access to Tobacco. On February 28, 1997, the FDA made 18 the minimum age to purchase tobacco products nationwide and required photo I.D.s for anyone under the age of 27.

Courts Affirm the Clinton Administration's Efforts To Protect Our Children from Tobacco. On April 25, 1997, a Federal District Court in North Carolina affirmed the FDA's authority to regulate tobacco as a drug and restrict children's access to tobacco products.

Protecting Federal Employees. On July 31, 1997, President Clinton announced an executive order to protect federal employees from environmental tobacco smoke. This executive order banned smoking in federal Executive Branch facilities.

"Bill Clinton has shown more guts on this issue of tobacco, children and health than any president in the history of the country."

--Joseph Califano, health secretary under President Carter and President of the Center on Addiction and Substance Abuse, August 11, 1995

THE WHITE HOUSE AT WORK

September 17, 1997

PRESIDENT CLINTON ANNOUNCED HIS PLAN FOR COMPREHENSIVE TOBACCO LEGISLATION TO PROTECT AMERICA'S CHILDREN

President Clinton challenged Congress to pass sweeping tobacco legislation to reduce teen tobacco use significantly. That legislation will build on the extraordinary efforts of the nation's attorneys general, who helped create an historic opportunity for progress in reducing smoking, especially by youth. Today, the President announced five key elements that must be at the heart of any national tobacco legislation:

1. A Comprehensive Plan to Reduce Youth Smoking, Including Tough Penalties If Targets Are Not Met. The central goal of tobacco legislation must be a comprehensive, nationwide effort to reduce teen smoking. The Administration is calling for:

- **Tough Penalties and Price Increases to Reduce Youth Smoking:** The Administration believes tobacco legislation must include stiff penalties that give the tobacco industry the strongest possible incentive to stop targeting kids. Legislation should set ambitious targets to cut teen smoking by 30% in 5 years, 50% in 7 years, and 60% in 10 years, and impose severe financial penalties that hold tobacco companies accountable to meet those targets. **Today, the President called for a combination of industry payments and penalties to increase the price of cigarettes by up to \$1.50 a pack over the next decade as necessary to meet youth smoking reduction targets.**
- **A Public Education and Counter Advertising Campaign:** Legislation must provide for a nationwide effort to deglamorize tobacco, warn young people of its addictive nature and deadly consequences, and help parents discourage their children from taking up the habit.
- **Expanded Efforts to Restrict Access and Limit Appeal:** The Administration supports legislation codifying the FDA's efforts to reduce youth access to tobacco, and imposing even stronger restrictions on youth access and advertising consistent with the Constitution.

2. Full Authority for FDA to Regulate Tobacco Products. The Administration supports federal legislation that affirms efforts by the Food & Drug Administration (FDA) to regulate tobacco like any other drug or device and that provides FDA with sufficient flexibility to meet changing circumstances.

3. The Tobacco Industry Must Change The Way It Does Business. The President called for the tobacco industry to stop marketing and promoting tobacco to children, provide broad document disclosure -- especially of those documents relating to marketing tobacco to children, and set up comprehensive corporate compliance programs that will reinforce the incentives created by the youth smoking penalties.

4. Progress Toward Other Public Health Goals. Federal tobacco legislation provides an opportunity to meet other public health goals: the reduction of second-hand tobacco smoke, the expansion of smoking cessation programs, the strengthening of international efforts to control tobacco, and the provision of funds for health research.

5. Protection for Tobacco Farmers and Their Communities. The Administration is committed to working with members of Congress in both parties to ensure that we protect the financial well-being of tobacco farmers, their families, and their communities.

REVISED

Tobacco - settlement -
general

**PRESIDENT WILLIAM J. CLINTON
TOBACCO LEGISLATION PLAN '97 SEP 17 AM 10:04
THE OVAL OFFICE
SEPTEMBER 17, 1997**

Acknowledgments: Vice President Gore; Secretary Shalala; Secretary Glickman; Bruce Reed; David Kessler; Dr. Koop; Members of Congress; Matt Meyers; Attorneys General: Mike Moore, Christine Gregoire, Bob Butterworth, Grant Woods and Skip Humphrey; heads of AMA, American Cancer Society and American Heart Association.

Good morning. Today I want to talk about one of the most important things we must do to keep our country strong and growing into the 21st century. This is a time of prosperity, hope and optimism for our country. Building on our balanced budget, we have much more to do. And as we prepare to enter a new century and a new millennium, it is clear: the health of our nation is absolutely dependent on the health of our people -- and especially the health of our children.

That is why one year ago, I launched the nation's first-ever comprehensive program to protect children from the dangers of tobacco, by reducing youth access to tobacco products and preventing companies from advertising to our children. The purpose of this rule was to reduce youth smoking by 50 percent in seven years. Earlier this year, a federal judge in North Carolina agreed that the FDA has the authority to regulate tobacco products to protect the health of our children.

These victories for the public health, along with the aggressive efforts of the state attorneys general, drove the tobacco companies to the bargaining table and extracted concessions from them that would have been unimaginable just a short time ago. I want to say a special word of thanks to the Attorneys General and others who negotiated this settlement: We wouldn't be here today if not for their foresight and determination. We now have an unprecedented opportunity to enact comprehensive tobacco legislation, working with members of Congress, the attorneys general, the public health community, tobacco farmers and others. We have moved from confrontation, denial and inertia to the brink of action on behalf of our children.

Today, I want to challenge the Congress to build on this historic opportunity by passing sweeping tobacco legislation that has one goal in mind -- the dramatic reduction of teen smoking. In the coming weeks I will invite Congressional leaders from both parties to the White House to launch a bipartisan effort to enact federal tobacco legislation. There are five key elements that must be at the heart of any national tobacco legislation.

Reducing teen smoking has always been this Administration's bottom line. Now it must be the industry's bottom line. That is why I believe that the first thing any tobacco legislation must include is a comprehensive plan to reduce teen smoking, including tough penalties. These penalties should be non-deductible, uncapped and escalating to give the tobacco industry the strongest possible incentive to stop targeting kids. One of the surest ways of reducing youth smoking is to increase the price of cigarettes.

Today, I am calling for a combination of industry payments and penalties to increase the price of cigarettes by up to \$1.50 a pack over the next decade as needed to meet our youth reduction targets. And I call on the House to follow the lead of the Senate and repeal the provision giving the tobacco industry a \$50 billion credit.

Second, any legislation must affirm the full authority of the FDA to regulate tobacco products. I believe that the FDA's jurisdiction over tobacco products must be as strong and effective as its authority over other drugs and devices. In particular, legislation cannot impose any special procedural hurdles on FDA regulation of tobacco products.

Third, effective legislation must include measures to hold the industry accountable for past misconduct, especially efforts to market products to children, while insisting that it change the way it does business. I ask the industry again to make a voluntary commitment to stop advertising to children. And I call on Congress to pass legislation providing for broad document disclosure so that the public can learn everything the tobacco companies know about the health effects of their products and their attempts to market to children.

Fourth, federal tobacco legislation must aim not only to reduce youth smoking, but to meet other health goals. These include the reduction of second-hand tobacco, the expansion of smoking prevention and cessation programs, the strengthening of international efforts to control tobacco, and the provision of funds for medical research and other important health objectives. We must build on the bipartisan agreement to fund children's health care that was in the recent balanced budget.

And finally, any tobacco legislation must protect tobacco farmers and their communities. We know that tobacco farmers are honest, hard working citizens, most of whom live and work on small, family farms. In some states, entire communities rely on income from the tobacco crop. Any legislation must protect these tobacco farmers, their families and their communities from the loss of farm income.

I want to thank Vice President Gore, who cares so passionately about this issue and has played such a key role in our efforts to protect our children from the dangers of tobacco. I have asked him to take the lead in building broad bipartisan support around the country for our plan. I also want to thank Secretary Shalala, Secretary Glickman, and Bruce Reed of my Administration and all those who have worked so hard to bring us to this point.

Let me be clear: this is not about money or how much we can extract from the tobacco industry. It is about fulfilling our duty as parents and responsible adults to protect our children from the dangers of tobacco. We are doing everything we can to give parents the tools to protect their children. But parents must be our partners in this effort. I challenge every parent in America to talk to your children about the dangers of tobacco, illegal drugs and other things that can hurt them. If our generation takes responsibility, we can send the next generation into the new century stronger and healthier than any before.

Thank you.

9-9-97 Tobacco Industry Meeting
FDA - Ingredients
Documents
Loebach
Process

1. FDA Jurisdiction

econ costs included - OK?

outweigh language -

I said - we'll redo - consider all costs etc.

make clear not necessarily not dispositive

2. Ingredients

90-day period

see new sheet

3. Documents

Disclosure to FDA of health-related docs, non/standing priv??

Problem -- really classic wk-product/principle

any subst. scientific info not already part of pub

domain - but not docs.

want give docs to FDA.

want to give out info itself.

BL idea:

Put out all info - ^{identify} docs.

Give panel initial func.

not already

only in public domain??

of comparing to

Me - no-need data dump.

real docs

Penalties outrageous for non-disclosure.

Has to be exclusive - or at least until ~~the~~ 3-judge panel retains judgment.

Panel can be composed in whatever ^{way} you want within reason.

4. Lookback -

80m at 1st track

160m at 2nd track

Tobacco - settlement - general



Bruce N. Reed
07/07/97 09:58:36 PM

Record Type: Record

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

cc:

Subject: Race and tobacco

I found the data on race, tobacco and drugs.

Tobacco use among 12th graders, 1994-95:

Whites, 24%
Hispanics, 12%
Blacks, 6%

Drug use among 12th graders, 1994-95:

Whites 24%
Hispanics 21%
Blacks 18%

Why the big difference?

The global warming constituency is entirely young people, aged 18-25, who rated global warming as high as education. The rest of the electorate had little or no concern for this issue.

Tobacco Agreement

The dynamic of this settlement is simple: more from the tobacco companies will always be viewed by the public as better. And the goal of every one of the hands it passes through is to place a unique stamp shaping the agreement. Deductibility is a strong issue in the public's mind, though the Republicans appear to have gone in the opposite direction.

Much of this is how it is viewed – is this a major settlement of the issue that protects children from Tobacco, or is this a cash cow for financing social programs? If it is the first, then we should make changes consistent with that objective. If it is the second, then we could try to push the tobacco companies to the limit.

If the settlement itself is supported by us and enough of the health groups, it will be accepted by the public. We, and not the Republicans are the major stamp of approval for this settlement.

It seems that no modifications would not make sense – Congress would then strengthen the settlement and we would seem too closely aligned with the Tobacco companies; Modest changes, along the lines of our tobacco objectives, which would get us the 21st Century Medical Science Research fund, strict regulation of nicotine and strengthened penalties for teen smoking, are most consistent with the original objectives of the effort and are unlikely to endanger the settlement. Some additional changes by Congress would be expected given the dynamic of piling on the tobacco companies.

Polling update:

Awareness for the tobacco agreement is at 82%. This compares to 66% awareness on August 4.

66% have heard about the proposed settlement, a 20% decrease since July 15.

Unaided, 41/43 support/oppose a settlement with the tobacco industry, a ten point drop since August

Awareness	7/1	7/15	8/4	9/9
Heard	82	86	66	82
Haven't heard	15	11	34	17

Unaided support	7/1	7/15	8/4	9/9
Support	53	52	51	41
Oppose	31	33	35	43

The level of support is consistent across parties and demographic groups
Unaided Support (9/9): Democrat: 41/43, Republican, 45/43, Independent: 40/46

45% of respondents say they will be more favorable to the President if he agrees to the settlement (14% much more + 31% somewhat), 39% unfavorable (18% much less + 21% somewhat).

Essentially, the supporters of the settlement have done a poor job at communicating the details of it. When explained to the public, it rises significantly:

“The settlement the tobacco companies have reached would allow the Food & Drug Administration to regulate nicotine, the tobacco companies would accept marketing regulations imposed by the government which would eliminate figures such as Joe Camel, and the tobacco industry would pay \$368 billion over 25 years. The \$368 billion fund would go to expand children’s health care and fund anti-smoking advertising, programs to help smokers quit, anti-smoking efforts targeting children, and compensatory damages to smokers and their families. In return, the settlement places limits on lawsuits against the tobacco companies, and allows the sale of cigarettes for at least 12 years. Given this, would you strongly favor, somewhat favor, somewhat oppose, or strongly oppose a settlement with the tobacco companies?”

Aided, support for the settlement increases 16 points to 57/38

57% favor (28% strongly + 29% somewhat)
 38% oppose (22% strongly + 16% somewhat)

Support is stronger among families:

Support/Oppose: Children at Home: 64/32, No children 54/40

Opposition from smokers is not significantly stronger than non-smokers:

Support/Oppose: Smokers: 54/39, Non-Smokers: 59/36

Do you think that the President should:	
Accept the settlement as is	21
Reject the settlement	19
Say he will accept it if changes are made to strengthen the penalties for failing to meet targets for reduction in teen smoking and strengthening regulation of nicotine	33
Say he will accept it only if major changes are made to greatly increase the money that tobacco companies would pay by several hundred billion dollars	14

33% say the agreement is too weak on tobacco companies, 20% say too tough and 40% just about right.

	Too tough	Too weak	Just about right
Democrats	15	37	44
Republicans	23	26	40
Independents	19	36	39
Men	27	34	32
Women	14	32	48

Respondents in the South are more likely to think the agreement is too tough

Region	Too tough	Too weak	Just about right
Northeast	13	35	48
Midwest	13	33	46
South	26	26	39
Farm	11	40	45
West	28	39	27

If the President said the settlement was not strong enough and pressed for a stronger deal, 56% would be more favorable and 32% would be less favorable.

“President Clinton and The White House have said that the provisions of the settlement are not strong enough, and will not endorse the deal unless federal regulatory authority over tobacco are strengthened, penalties for failing to meet targets for reductions in teen smoking are increased and the overall cost to the industry be raised.”

47% trust President Clinton more to reach a settlement with the tobacco companies versus 35% for Republicans in Congress. When asked to choose between Democrats and Republicans in Congress, the gap widens to 20% (47% Dem/27% GOP).

Support for the settlement rises when respondents are asked:

“The President will propose specific changes to the settlement next week. If the tobacco companies agree to this settlement with the changes proposed by the President would you strongly support, somewhat support, somewhat oppose or strongly oppose a settlement with the tobacco companies?”

**67% support (32% strongly + 35% somewhat)
24% oppose (13% strongly + 11% somewhat)**

This is the scenario that works for us – changes that are in line with our policies and that the tobacco companies accept. The deal is done, and this chapter is closed.

52% would support the settlement (40% oppose) even "if Congressional Democrats like Ted Kennedy and activists like David Kessler say these changes are not strong enough and we need to go much further in penalizing the tobacco companies beyond the 368 billion."

But from a public perspective, one issue that is hard to defend is the tax deductibility of the settlement:

69% do not believe the tobacco companies should be able to deduct the cost of the settlement from their taxes as a cost of doing business (24% say yes). Even when you say that changing this would bring the cost to the tobacco companies to \$500 billion and possibly end the deal, 57% still are against deductibility. This suggests another area for changing the settlement – making the penalty portion non-deductible, while leaving the other portions of the settlement as deductible, to put in to practice the principle that the companies would not be able to force any of the health care reimbursements on the taxpayers. This could be done for a modest increase in the settlement.

When told "that making it non-deductible would put the cost to tobacco companies at over \$500 billion and possibly end the settlement," still 57% oppose making the cost deductible, 33% favor

59% oppose the provision in the balance budget agreement "that would allow the tobacco industry to deduct \$50 billion raised from the new federal excise taxes from the amount of payment agreed to in the tobacco settlement" (28% oppose).

56% believe that if Congress does not agree to eliminate the \$50 billion tax break the \$50 billion should be added to the cost of the settlement to the tobacco companies, 33% do not.

Cutting down on teen smoking is the most important objective, and parental involvement is believed to be the most effective way to reduce teen smoking by a wide margin

What do you think the most important goal for President Clinton should be in the tobacco deal:	
Reducing teen smoking to the point that only adults in the country smoke	24
Ensuring that the government and tax payers are not paying for the implications of smoking	19
Penalizing tobacco companies to the point they are put out of business	17
Allowing strict federal regulation of nicotine	17
Compensating states for the costs incurred to treat people who used tobacco	9
Compensating people who have been hurt by tobacco	5

Raising the price of cigarettes was not seen as the most effective way to stop teen smoking:

What is the most effective way to reduce teen smoking:	
Parents playing more of a role in preventing smoking by their children	46
Increase educational efforts through advertising on the dangers of smoking	28
Banning advertising to minors by tobacco companies	11
Raising the price of a pack of cigarettes	10

20% of respondents believe that adults who choose to smoke are entitled to compensation for health care as a result of illnesses resulting from smoking. 76% say they are not entitled to compensation. (Kind of makes you wonder why the tobacco companies are settling at all.)

Having the support of health organizations is critical in persuading the public about the settlement.

For the following people or organizations, please tell me how important their opinion is to you on whether this is a fair settlement with the tobacco industry. For each one would you rate their opinion on the settlement as very important, somewhat important, somewhat unimportant or very unimportant?

<i>Ranked by very important</i>	Very Imp	Total Imp	Total Unimp
American Lung Association	72	95	2
American Heart Association	72	94	5
American Cancer Society	71	95	3
American Medical Association	61	91	7
State Attorney Generals involved in the negotiations	46	77	18
Former Surgeon General C. Everett Koop	44	74	19
President Clinton	44	74	24
Donna Shalala, Secretary of the Department of Health and Human Services	37	73	18
Vice President Gore	26	63	32
Congressional Democrats	25	69	25
Tobacco company executives	20	40	58
Congressional Republicans	19	65	29
Newt Gingrich	15	44	47

Tobacco - settlement

Tu/Fri/Mon - Skidala cont.

Telecom K. Thurn 7/31

Skidala

- Tomorrow -
- Monday -

- FDA jurisdiction / key ✓
 - advertising
 - ETS
 - Penalties / lookback ✓
 - Document disclosure ✓
 - Liability view ✓
 - \$ - at least level
 - farmers
- international -

✓ = controversial

not exhaustive - in terms of scope

- review process
- issues
- leg info/strategy



Elizabeth Drye

07/24/97 07:25:05 PM



Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Jerold R. Mande/OSTP/EOP

cc:

Subject: Gov. Locke (D-WA)

Governor Locke's general counsel called me to let us know the Governor will send a letter to the President Monday urging him to voice his support soon for the settlement with little modification. Locke's GC wanted to know where the President will be to minimize any difference between the governor and the President. I told him the President has only reached one conclusion re. black market.

I don't think this pending letter creates any problems, do you?

Also, the GC and I both are wondering if any other elected officials besides AGs have taken positions on the settlement. Do you know of any?

- o **Bliley, Dingell Slam EPA; Charge Twenty Percent Of US Counties Will Fail To Meet New Air Quality Standards.** House Commerce Committee Chairman Tom Bliley and ranking member John Dingell today blasted the EPA, saying the EPA now "admits" that its new air quality standards will result in 634 US counties violating the new levels. Of the 634, 546 counties will fail to comply with the new ozone standards and 283 will fail to comply with the new particulate matter standards (some will violate both). According to a statement released by the committee, EPA had estimated only two weeks ago that only 430 counties would be in violation of the new rules. According to the statement, Bliley said the 634 counties in violation "represent about 20 percent of the 3,200 counties in the United States."

A Commerce Committee source said this morning that the new data came to light after EPA finally submitted documents the committee has repeatedly requested. In issuing these findings, Bliley said in a statement, "Americans have a right to know if the county they live in is about to undergo massive new lifestyle restrictions at the behest of the EPA." Dingell also issued a statement, saying, "I'm perplexed and disturbed by EPA's apparent reluctance to inform the Congress and the public about the consequences of these new standards. One look at this list makes it perfectly clear why the US Conference of Mayors overwhelmingly adopted a resolution in opposition to the standards."

However, an EPA official strenuously rejected the contention, saying it is "inaccurate and invalid." The EPA official explained that extrapolate future compliance based on old data, saying, "The lists that are out there now are historical lists. In other words, they are dated, they are old, they are based on data from a while back." The official added, "Part of the reason that the Administration included a very detailed implementation plan when the standards went into effect was to obtain the new data that will be necessary to make the determinations with regard to which counties are in attainment and which counties are not in attainment. Until that is done, over a period of time, at this point, no one knows for sure which counties will be in and which will be out." The official concluded that EPA documents being cited by the Commerce Committee "don't purport to show which counties will be out under the new rules."

The EPA official further noted that the implementation plan for the new rules provide, "if certain components go into effect...that a lot of counties are going to be falling into attainment, even for the new rules." The official added that a key implementation component is "regional controls," which if a "state plan for regional air pollution control goes into effect, that's when we would expect to see a significant number of counties in attainment even for the new standards." The official also noted that he had never heard the previous EPA estimate cited by the committee of 430 counties potentially violating the new standards, while acknowledging that EPA does not have any numerical estimate of how many counties might meet the new standards because of special components, like regional controls, in the implementation plan.

- o **Congress Appears To Keep Slow Pace On Review Of Tobacco Deal.** As Senate committees this week continue to review the proposed tobacco litigation settlement, action on the matter appears to remain on the back burner for Congress. The deal must be approved by Congress in order for it to move forward.

The Senate Commerce, Science and Transportation Committee is holding hearings on the matter today, and the Senate Judiciary Committee is scheduled to hold its third hearing on the issue tomorrow. At the opening of today's hearing, Chair John McCain said the Commerce Committee plans "to meet early in October and decide at that point where and in what direction we would like to take legislation on this very important issue." A Senate GOP source close to the issue said Senate Judiciary Committee Chair Orrin Hatch has asked his committee's "legislative counsel to draft the settlement into legislative language, so it can be evaluated. But that has not been completed yet." The source said Hatch's committee is interested in studying "not just the legal ramifications, but other areas of this issue, like public health goals, efforts to reduce teen smoking, commercial enterprises which market tobacco, and the advertisers."

A White House task force formed to review the settlement deal has been asked by President Clinton to complete its review by mid-August, but several sources have voiced skepticism that the deal will be fully evaluated by that deadline. Although Speaker Newt Gingrich last week mentioned the formation of a House task force to study the proposed settlement, the Senate source said no such group has yet been

Participants in Friday, July 24, 12:45pm Tobacco Meeting:

Purpose: To hear from state and local officials who have been fighting on the frontlines.

1. **Gregory N. Connolly, D.M.D., M.P.H.** of Massachusetts.

Gregory Connolly is **Director of the Massachusetts Tobacco Control Program**. Massachusetts, along with California, has received national recognition for reducing tobacco use, especially among young people, by enacted a tobacco excise tax that has generated funding for a statewide counter advertising campaign. Dr. Connolly is also credited with passage of the 1986 federal law on smokeless tobacco, and was awarded the Surgeon General's Medallion for National Leadership by Dr. C. Everett Koop in 1987. He has testified before Congress on numerous occasions, and appears regularly on major national news shows.

2. **Donna Grande, M.G.A.** of Arizona.

Donna Grande is **Director, of Full Court Press** in Arizona -- a 5 year, \$3.5 million, program funded by the Robert Wood Johnson Foundation, to develop a successful prototype to reduce youth smoking by 10 percent. From 1991-1996, Ms. Grande ran Project ASSIST in Arizona.

3. **Sally Herndon Malek, M.P.H.** of North Carolina.

Sally Herndon Malek is **Manager of Project ASSIST** in the North Carolina Department of Health. She has been with the project since its inception. Sally serves as Chair of the Association of State and Territorial Health Officers' (ASTHO) Tobacco Prevention and Control Network.

4. **Randy Schwartz, M.S.P.H.** of Maine

Randy Schwartz is **Director of Community and Family Health**, with the Maine Bureau of Health, and has run Project ASSIST in Maine since it began in 1991. Mr. Schwartz has worked with numerous federal, state, and local tobacco control efforts.

5. **Peter Zollo** of Illinois

Peter Zollo is **President and Co-founder of Teenage Research Unlimited** the first market research firm to specialize exclusively in teenagers. Peter has worked extensively on teenage cigarette smoking cessation and the development of counter-advertising. He is on the Columbia University School of Public Health, Tobacco Counter-Marketing Panel, and has conducted research and consulted for the State of Massachusetts in its counter-advertising campaign.

ASSIST

NCI's American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) project, represents a joint effort among NCI, the American Cancer Society, and health departments in 17 states. During the first 24 months of the project (1991-1993), each state conducted a detailed site analysis and needs assessment. Following a careful review of these findings, each state developed its own comprehensive 5-year smoking control plan. In the intervention phase (1993-1998), each state has been implementing their plan. State programs rely on proven interventions in work sites, health care settings, schools, community groups, and mass media. Detailed guidelines and extensive training has been continually provided to ensure that all interventions used in ASSIST are consistent with current scientific knowledge. While prevention and cessation services are an integral component of any comprehensive effort, in ASSIST emphasis is placed on the strategic use of media and the adoption and implementation of those smoking control policies that support nonsmoking as the accepted community norm. ASSIST also relies on a coalition based model. To date, more than 2,000 community organizations have



U.S. Department of Justice

Office of the Associate Attorney General

Tobacco - instruments

Washington, D.C. 20530

FACSIMILE TRANSMITTAL COVER SHEET

DATE: July 15, 1997

TO: Elena Kagan

FACSIMILE NO: 456-2878

TELEPHONE NO: 456-5584

FROM: John C. Dwyer

FACSIMILE NO: (202) 514-0238

TELEPHONE NO: (202) 514-9500

NO. OF PAGES: 4 (w/cover)

COMMENTS: I would like for you to review the attached.

We would like to mail it out before the hearing tomorrow.

I would really appreciate hearing from you by 4 p.m. today

if at all possible. Thanks.



Office of the Attorney General
Washington, D.C. 20530

The Honorable Richard J. Durbin
United States Senate
Washington, DC 20510

Dear Senator Durbin:

Thank you for your letter suggesting that the Department of Justice file a legal action to recover certain tobacco-related health care costs. I apologize for the delay in responding.

I certainly agree that smoking is a major public health issue whose impact, in terms of lives lost, illnesses caused, and costs to our health care system, has been devastating. In addressing this issue, the Department of Justice has strongly defended the regulations issued by the Food and Drug Administration ("FDA") to keep tobacco products, and the advertising of these products, away from children. The recent district court decision upholding the FDA's authority to regulate tobacco was an important victory in this ongoing battle.

Your letter emphasizes that the Federal Government has incurred health care costs related to tobacco use under Medicaid, Medicare and several other Federal health programs. As you know, pursuant to the Medicaid law, there are now 40 states that have sued tobacco companies to recoup health care costs incurred for tobacco-related diseases. The Department of Justice, along with the Department of Health and Human Services ("HHS"), which oversees the Medicaid program, has closely monitored this litigation. Under the Medicaid statute, the states are authorized to pursue recovery of health care expenses from third parties who are legally liable for these costs. We have been in contact with many of the State Attorneys General who have brought suits and have kept them updated about the status of our defense of the FDA regulations. We have also responded to their inquiries and requests for assistance.

Since the Medicaid program was designed to be primarily administered by the states, the Medicaid law does not include a provision which would allow the Federal Government to pursue such recoveries directly. However, because the Federal Government does pay a significant portion of the cost of the Medicaid program, Congress protected the Federal Government's interest in

The Honorable Richard J. Durbin
Page 2

any third party suits the states bring by requiring the states to reimburse the Federal Government its portion of any recovery.

On June 20, 1997, the states announced that they had reached a proposed settlement of their pending Medicaid claims against tobacco companies. The terms of that proposed settlement would require Federal legislation to implement the compromise. The Administration is currently reviewing the proposed settlement. As part of that review, the impact of the proposed settlement on the Federal interests associated with the Medicaid program is being considered.

With respect to the other Federal interests referenced in your letter, the Medicare statute does not contain an explicit authorization for the Federal Government to bring direct actions against third party tortfeasors comparable to the express authorization provided the states by the Medicaid statute. Under the Medicare program, when a beneficiary brings an action and is successful, HHS is entitled to the portion of that recovery which represents the medical bills that the program paid. Because of this, HHS protects the program's interests by notifying beneficiaries who are bringing tort actions themselves that they have a responsibility to reimburse the Medicare program out of any recovery. Thus far, however, the Department and HHS have not believed it was advisable to attempt to recoup Medicare costs caused by tobacco-related diseases through direct litigation. Obviously, however, Federal interests under Medicare may be implicated by the recent proposed settlement of the states' suits against the tobacco companies, and the Administration's review of the proposed settlement will certainly consider any such impact.

Finally, as to health care services that Federal agencies directly provide, the Government has the legal authority to pursue an action against a third party tortfeasor whose conduct causes harm to a program recipient. Currently, the agencies providing medical care have not collected the information necessary to assess the feasibility of such suits. Instead, as is done with the Medicare and Medicaid programs, they protect the Government's interests through subrogation claims in any successful actions brought by the programs' recipients rather than bringing such actions directly.

Here again, Federal interests under these other Federal agency health care programs may be implicated by the recent proposed settlement of the states' Medicaid suits. You may be assured that the issues raised by your letter will be considered during the Administration's review of the proposed settlement.

The Honorable Richard J. Durbin
Page 3

As always, thank you for sharing your views about these important issues. We will certainly keep them in mind during the Administration's review of the options presented by the proposed settlement.

Sincerely,

~~Janet Reno~~ Ann Harkins

Tobacco - settlement

- Q: Can you say any more about the tobacco settlement now that your staff have had more time to review it?**
- A.** I have reached a final conclusion on only one part of the settlement: the requirement that the FDA find that there will not be a black market before mandating any product changes. That is an unreasonable requirement, which will too greatly limit the FDA's ability to make tobacco products safer or less addictive. My staff is still reviewing the settlement proposal, and I have not reached any further conclusions. As I've said before, the settlement proposal provides an historic chance to further protect our children and our country from the dangers of tobacco. We must and will respond to it in a way that best advances the public health.
- Q. Some of your staff are saying that the penalties tobacco companies must pay if they fail to meet the targets for reducing children's smoking are too soft -- that those penalties must be increased or companies will still profit from hooking kids.**
- A.** I know that my staff are looking into this. We have to ask tough questions. We have to make sure the settlement holds industry accountable for reducing the number of children who start smoking. I will be looking carefully at this question.
- Q. Your advisors are meeting today with industry representatives. What do they expect to get out of this meeting?**
- A.** Secretary Shalala and Bruce Reed will ask the industry a lot of tough questions. They will let them know we will not just rubber stamp this agreement, and they will make it clear that the bottom line for my Administration is ensuring that any agreement is good for the public health, and particularly the health of our children.

June 26, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Tobacco Settlement Review Process

This memo sets forth the process we will use to evaluate the proposed tobacco settlement and to present recommendations to the President. Our goal is to prepare an analysis for the President by late July that defines our public health and public interest objectives; weighs the settlement's strengths and weaknesses against those objectives; summarizes the views of the public health community, Congress, and other affected parties; and lays out positions the President could take on the settlement proposal.

Interagency Review

The review will be carried out by four major workgroups which have already begun to meet:

- I. **Regulatory Issues** (convened by Elena Kagan). This group will look at: (a) FDA regulation of product content, including nicotine; (b) FDA regulation of access, advertising, and labeling; and (c) 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.
- II. **Program and Budget Issues** (convened by Chris Jennings). This group will examine proposed uses of settlement funds, including programs to reduce smoking and expand children's health care coverage. In particular, the group will consider the use of settlement funds for: (a) children's health care; (b) education efforts (including grass roots programs); (c) smoking cessation programs; and (d) investments in health research, including nicotine research. White House offices are DPC, OMB, NEC, OVP, and OSTP. Participating agencies are HHS, Treasury, DOL, USDA, Interior, VA, and DOD.
- III. **Legal Issues** (convened by Elena Kagan). This group will review the settlement's provisions on liability, damages, and document disclosure, and will consider constitutional, antitrust, and other legal issues raised by the settlement. White House offices are DPC, OVP, NEC, and Counsel. Participating agencies are DOJ, HHS, Treasury, EPA, and Interior.

IV. Industry Performance and Accountability (convened by Bruce Reed). This group will analyze the economic effects of a settlement. The group will assess: (a) the economics of the industry and the settlement's effects on industry performance, international markets, federal revenues, consumers, farmers, etc.; and (b) the set of incentives and penalties in the settlement to reduce tobacco use, especially by children. On a separate track, Dan Tarullo will oversee a look at Administration policy on tobacco-related trade and international issues, which the settlement does not directly address. White House offices are DPC, NEC, CEA, OVP, OMB, and OSTP; participating agencies are: HHS, Treasury, DOL, USDA, USTR, State, and DOD.

Public Outreach

We will work with OPL and HHS on a tightly focused public outreach effort designed to demonstrate that the President is conducting a thoughtful, thorough review focused on public health issues. Many groups covering a wide range of interests are affected by the proposed settlement. We will emphasize the President's focus on health by hosting 6-8 highly visible White House meetings with small, select groups of health experts. Working with OPL, we will encourage other interested groups (e.g., children's advocates, women's organizations, and farmers) to share their views through written comments and, where appropriate, meetings with agency and White House staff.

Donna and I will host the White House meetings over the next three weeks. We will convene experts from national health organizations; Koop-Kessler advisory group participants; experts on tobacco products and nicotine addiction; local grass-roots advocates; state and local tobacco control officials; and children's health advocates.

We will start by bringing in members of the Koop-Kessler advisory group, including the American Cancer Society, American Medical Association, and American Heart Association, the week of July 7. Future meetings will include: Action on Smoking and Health; American Academy of Pediatrics; American Public Health Association; Americans for Nonsmokers' Rights; and National Center for Tobacco-Free Kids, Joe Califano, and leading academics.

Congressional Outreach

We will need to take into account Congressional views on the settlement proposal. Multiple committees in both the House and Senate would have jurisdiction over legislation enacting an agreement. The goal of our Congressional outreach process will be to strengthen relationships on the issue with key members and to keep the debate bipartisan and balanced. We will consult with the leadership, anti-tobacco advocates, and representatives of tobacco states. Today and tomorrow HHS is making calls to key Republican and Democratic members to seek their input on how best to consult with the Hill in the coming weeks. We are working with Legislative Affairs and HHS on a detailed list of Congressional meetings to begin the week of July 7. There are many critical members, including Senators Lott, Daschle, Hatch, Kennedy, Lautenberg, Ford, and Durbin; and Congressmen Gephardt, Gingrich, Bliley, Waxman, Dingell, Hansen, Meehan, Gordon and others.

Press Plan

This issue is certain to attract considerable press attention throughout our review. Major news organizations have assigned entire teams to cover the tobacco settlement. After devoting so much coverage to the negotiations, the networks are determined to keep this issue alive. We should take advantage of that heightened interest to advance our public health message.

On Friday, Donna and I are prepared to brief the White House press corps on how we will conduct this review, who will be involved from within the Administration, and what groups and outside experts we plan to consult.

During the week of July 7, while the President is away, Donna and I will conduct the public health and Congressional meetings described above. This will give the press something to write about, and show that we are running an open process. During the week of July 14, we will continue public health and Congressional meetings and bring in two groups of attorneys general - the enthusiasts and the skeptics. The Vice President is willing to hold a public hearing with us in mid-July if we need one.

Schedule

We have planned the following schedule. Some do not believe the review can be completed within 30 days, as the President suggested. But we will work as quickly as possible to preserve that option and ensure a decision by early August at the latest.

- Week of June 23: DPC convenes work groups and assigns analytic tasks to members.
Donna and Bruce brief press on process and conduct.
- Week of June 30: Groups provide preliminary assessments of key issues.
DPC and agency staff begin meetings with public health experts.
- Week of July 7: Groups develop options for key issues.
Bruce, Donna and others continue meetings with public health groups
and begin meetings with members of Congress.
- Week of July 14: Principals review workgroup assessments and meet to discuss options.
Bruce, Donna and staff continue meetings with public health experts
and Members of Congress.
Possible public hearing with the Vice President.
- Week of July 21: Initial meeting with the President.
- Late July/
early August: Presidential decision and announcement.

ELIZABETH DRYE GLICKMAN LTR | Tobacco -
amendment

Honorable Joe Skeen
U.S. House of Representatives
2302 Rayburn House Office Building
Washington, D.C. 20515

DRAFT received
6:05 PM 7/15/97

Elana - USDA
Wants comments/clearance by 8:30 am,
Wed, per my e-mail

Dear Joe:

I am writing concerning an amendment to the fiscal year (FY) 1998 Agriculture

Appropriations Act offered by Congresswoman Nita Lowey, which would prohibit the use of
funds to pay the salaries of personnel who provide crop insurance or noninsured crop disaster
assistance for tobacco for the 1998 and later crop years.

The Department of Agriculture (USDA) is strongly opposed to this amendment. Crop
insurance and noninsured crop disaster assistance programs comprise the principal remaining
safety net for farmers suffering crop losses from natural disasters, since the elimination of ad hoc
disaster aid. The adoption of this amendment will effectively end our ability to provide crop
insurance ~~AND NONINSURED ASSISTANCE PAYMENTS~~ subsidies for tobacco and would make crop insurance cost prohibitive for tobacco
growers. This would also adversely affect the cost of production for the thousands of tobacco
growers who must have insurance in order to get production assistance financing.

OSJA

✓

~~The scope of tobacco crop insurance availability in rural communities is quite large and is~~
an essential part of the producer "safety net" envisioned by this administration under an
agricultural policy that promotes "freedom to farm." The fact that tobacco is an integral part of
the economic infrastructure of many rural areas is evident when looking at the crop insurance
statistics for the 1996 crop year.

OSJA

USDA

69,800

PRODUCERS WITH

DEFINITION

There were some 89,000 tobacco crop insurance policies in force in 1996, with nearly 69,500 of those policies ~~carrying~~ *ACTUALLY PAID THE PREMIUM* premium for the year. Over 550,000 acres were insured with liability exceeding \$1.15 billion. Tobacco producers paid more than \$20 million in premiums to insure their crops in recognition of the need to provide for their own risk management at a time when the government is providing fewer and fewer farm subsidies.

is this the loss or crop insurance payment?

As a result of back-to-back hurricanes that hit the East Coast last year, tobacco losses in three states (North Carolina, South Carolina, and Virginia) amounted to \$77.8 million, which was 86 percent of all tobacco losses nationally for the year. This money helped communities recover from disaster and was paid for in part by the producers themselves. The significance of a program that encourages producers to assess their individual risk management needs and allows them to pay part of the cost for coverage must not be lost at a time when fewer dollars are available for other types of assistance. Elimination of tobacco crop insurance would place a greater burden on other sources of relief when disaster strikes.

This amendment would have a detrimental effect on thousands of small farmers in tobacco producing States, not to mention the toll it would take on the economic stability of many rural communities. The total value of the tobacco crop is approximately \$3 billion, and tobacco products provide a net foreign trade surplus of \$6 billion annually. The funds USDA proposes in the FY 1998 Agriculture Appropriations Act are for basic Government activities similar to those provided for other major commodities.

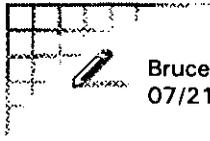
I urge you and your colleagues to vote against this amendment when it is considered by the House. Please contact me if you should need further information.

Sincerely,

DAN GLICKMAN
Secretary

cc: Honorable Marcy Kaptur
U.S. House of Representatives
2311 Rayburn House Office Building
Washington, D.C. 20515

09-3136215



Bruce N. Reed
07/21/97 04:15:44 PM

Record Type: Record

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

cc:

Subject: random ideas/questions

The following questions are not very important, just points of curiosity:

1. Licensing: can we do anything to impose penalties on underage youths who buy cigs? Suspend drivers license? Take away fake ID?
2. Why did we back away last year from zero-tolerance tobacco policies at schools?
3. For July 30, do we have a good list of ETS restrictions in various states and cities?
4. Do bus lines allow smoking?
5. Koop Kessler envisions an executive order to promote global adoption of US domestic tobacco control policies (see appendix 3, p. E5). Is this feasible? Does it mean anything?
6. KK also calls for strict penalties for tobacco smuggling. (appendix 3, p. E7). Does that make sense?

2/9/97 Tobacco mtg w/ AGs

1. Cigarette provision

Crepine - "significant" - can regulate on what this means.
scientific advisory board.

Myer - framework makes it more likely that FDA will regulate on this subject.

One reason - current std is "reas assurance of safety" - which is very difficult to apply to this products.

Crepine - tar + other ingredients even more imp.

There will be his lib. w/ this std - bec it makes sense for this product. NOT senarep in round table.

Shalala - Will other parties drop suits? EG - Adverts, retailers

Myer - Adverts will continue. But this is way to do the advert. restriction - through court decree.

Myer - These advertisers do so much more than do than to bacco. That's why hearing so little.

Shalala - "extraord circs" w/in 5 yrs.

Myer - Take a yr or two to go into effect - then wait for 3 yrs or so - see how it works

If af. our big loophole, a/c can write to cos: we're starting rulemaking: change now.

Shalala - licensing - like EPA. ^{CG} & ^{Fed} min std - states enforce it.

Myer - Purposefully left vague, so you can fill in.

CG: Current FDA penalties in place for any violation except for failure to disclose - 10x as much.

Penalties - brand-by-brand / industry-wide.

MM: our choice. Easy for a company to apply - but then have a mechanism for costs to allocate.

CG: ~~to~~ They don't care much about this.

Moore: No penalty now. This is a lot better. Basically forces costs to disgorge product.

SC: That's based on all sales.

This is and should be based on sales to kids.

Disclosure of documents

Myers - Can't have disclosure of all a-c, it will allow lawsuits.

Any citizen has right to challenge a priv claim.

Industry has waived proced. hurdles (used for p. b. case, etc)

so you get straight to substance.

Provision to create indices.

Shalala - How much flexib. do you have?

Moore - They can't lobby for anything weaker.

Some flexib, but not a whole lot. (espec on PBM)

Myers - As priorities get set - what's really imp to change - then can go back to companies + say need to do this to get WH support.

- FDA

- penalties

- something not tax deductible

CG - Drafting of bill immensely important. We can address this w/

ind as we go along. Part left vague so we could work
w/ you.

Memor: If it happens by January, we'll lose this op. FL + TX coming up.
TX will be tried if they don't see progress. MN - was made.
And if we lose, we're toast.

Myer - only half a dozen states w/ real cases.

Approaches / Priority Changes to Nicotine Regulation Provisions

I. Settlement proposal -- limited change

- o Maintain "significant reduction in health risk" findings and formal rule-making but remove insurmountable legal hurdles, e.g.
 - maintain risk reduction and technologically feasible standards
 - drop requirement to show no black market (for reducing/eliminating nicotine);
 - lower judicial review standard to arbitrary and capricious
 - eliminate requirement that in any judicial review, difference accorded the agency depends on the extent to which the matter at issues is in its field of expertise

II. Settlement proposal -- medium change

- o Maintain "significant reduction in health risk" finding; drop everything above plus
 - drop formal rulemaking
 - eliminate right to petition agency on black market finding
 - drop requirement to consider "demonstrated market acceptance" of alternative products (for nicotine elimination).

AA

- o ~~Set~~ ^{Keep} higher hurdle for nicotine elimination (but not for "equivalent actions")

III. Settlement proposal -- most change

- o Revert to FDCA regulatory and device mechanisms ~~and standard~~, but
 - agency shows (in normal proceeding) reduction in health risk, and considers technological feasibility, black market, # of dependent users, substitutes;
 - provide time period (5 years?) during which agency cannot eliminate nicotine or take "equivalent action."

reduce time period - increase hurdles ?

M E M O R A N D U M

TO: BRUCE REED, ELENA KAGAN
FROM: TOM FREEDMAN, MARY L. SMITH
RE: OUTLINE OF TOBACCO RESOLUTION FROM JUNE 20, 1997
DATE: JUNE 30, 1997

PREAMBLE

TITLE I: REFORMATION OF THE TOBACCO INDUSTRY

- A. RESTRICTIONS ON MARKETING AND ADVERTISING**
- B. WARNINGS, LABELING AND PACKAGING**
- C. RESTRICTIONS ON ACCESS TO TOBACCO PRODUCTS**
- D. LICENSING OF RETAIL TOBACCO PRODUCT SELLERS**
- E. REGULATION OF TOBACCO PRODUCT DEVELOPMENT AND MFGING**
- F. NON-TOBACCO INGREDIENTS**
- G. COMPLIANCE AND CORPORATE CULTURE**
- H. EFFECTIVE DATES**

TITLE II: "LOOK BACK" PROVISIONS/STATE ENFORCEMENT INCENTIVES

TITLE III: PENALTIES AND ENFORCEMENT; CONSENT DECREES; NON-PARTICIPATING COMPANIES

- A. PENALTIES AND ENFORCEMENT**
- B. CONSENT DECREES**
- C. NON-PARTICIPATING COMPANIES**

**TITLE IV: NATIONWIDE STANDARDS TO MINIMIZE INVOLUNTARY EXPOSURE
TO ENVIRONMENTAL TOBACCO SMOKE**

TITLE V: SCOPE AND EFFECT

A. SCOPE OF FDA AUTHORITY

B. STATE AUTHORITY

TITLE VI: PROGRAMS/FUNDING

A. UP FRONT COMMITMENT

B. BASE ANNUAL PAYMENTS

C. APPLICABILITY

D. TAX TREATMENT

**TITLE VII: PUBLIC HEALTH FUNDS FROM TOBACCO SETTLEMENT AS
RECOMMENDED BY THE ATTORNEYS GENERAL FOR
CONSIDERATION BY THE PRESIDENT AND THE CONGRESS**

TITLE VIII: CIVIL LIABILITY

A. GENERAL

B. PROVISIONS AS TO CIVIL LIABILITY FOR PAST CONDUCT

C. PROVISIONS AS TO CIVIL LIABILITY FOR FUTURE CONDUCT

TITLE IX: BOARD APPROVAL

APPENDICES

APPENDIX I: WARNINGS IN ADVERTISEMENTS

APPENDIX II: RETAIL TOBACCO PRODUCT SELLER PENALTIES

APPENDIX III: APPLICATION TO INDIAN TRIBES

APPENDIX IV: INDUSTRY ASSOCIATIONS

APPENDIX V: "LOOK BACK"

APPENDIX VI: STATE ENFORCEMENT INCENTIVES

APPENDIX VII: RESTRICTIONS ON POINT OF SALE ADVERTISING

**APPENDIX VIII: PUBLIC DISCLOSURE OF PAST AND FUTURE TOBACCO
INDUSTRY DOCUMENTS AND HEALTH RESEARCH**

SECTION BY SECTION ANNOTATIONS

PREAMBLE

TITLE I: REFORMATION OF THE TOBACCO INDUSTRY

A. RESTRICTIONS ON MARKETING AND ADVERTISING

- Canada imposed a ban on cigarette advertising in 1989. Since then, the percentage of Canadians who smoke has gone up from 30 to 31%. In Finland, teenage smoking has gone up from 22 to 24% since a partial advertising ban in 1978. (Chicago Tribune, 6-22-97)
- Experience in other countries shows that even where there are very tough restrictions, or even outright bans, on advertising and marketing, they have had little impact on smoking levels. Youngsters take up smoking because they perceive the habit as “cool,” not because advertisements tell them to. (Financial Times, 6-23-97)
- Teenagers say that Marlboro Man is not what persuades them to smoke, it is their peers. (USA Today, 6-25-97)
- Dr. Stanton Glantz, a professor of medicine at the University of California at San Francisco and author of “The Tobacco Papers,” believes that the proposed deal, by banning representations of the Marlboro Man, still leaves enough loopholes for both the tobacco companies and their advertisers. He believes the restrictions won’t make it that much harder to sell cigarettes. Even without the Marlboro Man, lots of Marlboro ads just show mountains or horses, and those aren’t banned. (Chicago Tribune, 6-22-97)

B. WARNINGS, LABELING AND PACKAGING

C. RESTRICTIONS ON ACCESS TO TOBACCO PRODUCTS

D. LICENSING OF RETAIL TOBACCO PRODUCT SELLERS

E. REGULATION OF TOBACCO PRODUCT DEVELOPMENT AND MFGING

- According to the proposed settlement, after 12 years, the FDA can require change in cigarettes. According to C. Everett Koop, settlement imposes 2 difficult barriers and one impossible barrier on FDA to change makeup of cigarettes. The difficult barriers are 1) modification of a tobacco product must be proved by the FDA to cause a significant reduction in risk and 2) such modification must be shown to be technologically feasible, not by the tobacco industry but by the FDA. No other industry is treated this way. The impossible barrier is the requirement that modification of tobacco will not cause a black market or smuggling. There is no way the FDA can prove a negative. There is no way the FDA can undertake to prove that with 50 million smokers. (USA Today 6-25-97)
- Advisory Committee on Tobacco Policy and Public Health: American Medical Association, American Cancer Society, American Lung Association, American Heart Association, American Academy of Pediatrics, American Academy of Family Physicians. Koop and Kessler group call settlement “unacceptable,” saying it undermines the Government’s ability to regulate nicotine in cigarettes. (NY Times, 6-26-97; Washington Post 6-26-97)
- Essentially nullifies the findings of a federal court this year that the FDA has a statutory right to regulate tobacco. Settlement actually postpones the issue of nicotine control for 12 years. (USA Today, 6-25-97)

F. NON-TOBACCO INGREDIENTS

G. COMPLIANCE AND CORPORATE CULTURE

H. EFFECTIVE DATES

TITLE II: “LOOK BACK” PROVISIONS/STATE ENFORCEMENT INCENTIVES

- See Appendix V.

TITLE III: PENALTIES AND ENFORCEMENT; CONSENT DECREES; NON-PARTICIPATING COMPANIES

A. PENALTIES AND ENFORCEMENT

B. CONSENT DECREES

C. NON-PARTICIPATING COMPANIES

TITLE IV: NATIONWIDE STANDARDS TO MINIMIZE INVOLUNTARY EXPOSURE TO ENVIRONMENTAL TOBACCO SMOKE

TITLE V: SCOPE AND EFFECT

A. SCOPE OF FDA AUTHORITY

B. STATE AUTHORITY

TITLE VI: PROGRAMS/FUNDING

- Cigarettes might go up 75 cents a pack. Some research shows that every 10% of price increase drives 12% of teen smokers to quit. (USA Today, 6-25-97)
- Poll shows that if settlement increases the cost of cigarettes by 75 cents a pack, 57% said that it would be somewhat likely to cause them to quit. 43% say the price increase would not impact their habit. (USA Today, 6-25-97)
- The 50-cents-a-pack price increase, more than any other aspect of the settlement, may affect people's propensity to smoke. Other countries have found that big price increases reduce demand for cigarettes, particularly among youngsters. Gary Black, an analyst with Sanford C. Bernstein, has estimated that the price increase could cut consumer purchases by 11%. (Financial Times, 6-23-97)
- Studies at the University of Chicago and elsewhere suggest volume sales could fall by as much as 8% for each 10% increase in prices. (Bergen Record, 6-21-97)
- If the settlement passes Congress, the companies could lose \$1.5 billion or so in profits next year, partly caused by lower sales and partly by interest on loans the companies will need to pay for the settlement. But the companies are still expected to make \$6.7 billion in profits next year, deal or no deal. (Chicago Tribune, 6-22-97)
- The tobacco settlement is like Prohibition --black markets will develop. Canada had to rescind the harshly punitive taxes it imposed on cigarettes when widespread trafficking across the border resulted in increased violence, intolerable demands on law enforcement and no declines in smoking. (WSJ, 6-26-97)

A. UP FRONT COMMITMENT

- Philip Morris will provide the majority of an initial \$10 billion (payment is based on stock market value) --Philip Morris will pay \$6.5 billion; RJR Nabisco will pay \$600 million (reflects RJR Nabisco's weaker financial position); Brown & Williamson (B.A.T.) will pay \$1.7 billion; Lorillard (Loews) \$720 million; and U.S. Tobacco (UST) \$324 million N.Y. Times 6-25-97

B. BASE ANNUAL PAYMENTS

- Pay-out averages \$14.7 billion a year, more than double the industry's operating profits of \$7.2 billion from domestic tobacco sales last year. Tobacco companies plan to offset the cost of the deal by increasing cigarette prices in the US by about 50 cents a pack, so the settlement will have the same effect as a big tax increase. The deal does nothing to impinge on the growth side of their business - their booming overseas sales, particularly in emerging markets. (Financial Times, 6-23-97)

C. APPLICABILITY

D. TAX TREATMENT

TITLE VII: PUBLIC HEALTH FUNDS FROM TOBACCO SETTLEMENT AS RECOMMENDED BY THE ATTORNEYS GENERAL FOR CONSIDERATION BY THE PRESIDENT AND THE CONGRESS

- Poll shows that 65% of smokers would be likely to sign up if the government were to provide free programs to help them quit. 33% would take a pass on free programs to help them kick the habit. (USA Today, 6-25-97)

TITLE VIII: CIVIL LIABILITY

A. GENERAL

B. PROVISIONS AS TO CIVIL LIABILITY FOR PAST CONDUCT

- According to Elizabeth M. Whelan, President of the American Council on Science and Health, the settlement would put a yearly cap of \$5 billion on damages -- an amount that is a trivial cost of doing business for the industry. The cap will serve as a disincentive for plaintiffs' attorneys. Under the settlement, the industry is afforded even more legal protection than it gained in 1965 when Congress slapped the so-called warning label on cigarette packs, thereby giving cigarette manufacturers a federally backed excuse not to give full disclosure of health risks. Now the industry, having paid tax-deductible damages, will be able to return to business as usual for the next 25 years. Removing the threat of litigation will bring to a halt many efforts to discourage smoking and curb the outrageous behavior of an industry. Her suggestion is to let the tobacco industry have its day in court. (WSJ, 6-26-97)

C. PROVISIONS AS TO CIVIL LIABILITY FOR FUTURE CONDUCT

TITLE IX: BOARD APPROVAL

APPENDICES

APPENDIX I: WARNINGS IN ADVERTISEMENTS

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APPENDIX IV: INDUSTRY ASSOCIATIONS

APPENDIX V: "LOOK BACK" youth smoking

- Koop and Kessler group say the proposed penalties on the nation's cigarette makers if they failed to reduce smoking levels among young people were far too small to have an impact. (NY Times, 6-26-97)
- \$2 Billion cap for reduction in youth smoking comes to 8 cents per pack of cigarettes sold annually, 3 cents of that is tax deductible, so the penalty is really 5 cents a pack (USA Today 6-25-97)

- The agreement provides for a financial penalty of up to \$2 billion a year against the tobacco industry if it fails to cut under-age smoking by 60% over the next 10 years - seemingly, a form of guarantee that the deal will work. But the target looks so unrealistic as to suggest that tobacco manufacturers consider an extra \$2 billion a year a price worth paying for the legal immunity they will gain. (Financial Times, 6-23-97)

APPENDIX VI: STATE ENFORCEMENT INCENTIVES

APPENDIX VII: RESTRICTIONS ON POINT OF SALE ADVERTISING

**APPENDIX VIII: PUBLIC DISCLOSURE OF PAST AND FUTURE TOBACCO
INDUSTRY DOCUMENTS AND HEALTH RESEARCH**

POLL RESULTS

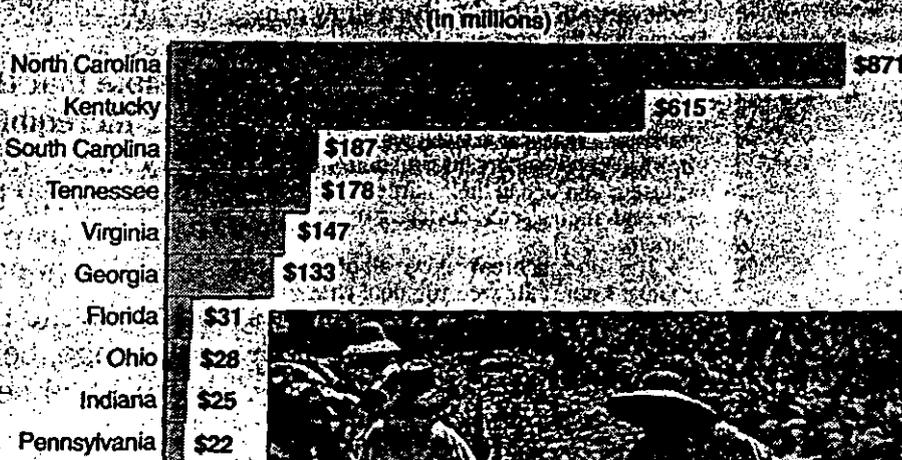
USA TODAY 6-25-97

	YES	NO
In the long run, do you think the settlement would:		
Lead to a significant reduction in smoking among adults	29%	50%
Lead to a significant reduction in smoking among teenagers	33%	45%
	APPROVE	DISAPPROVE
Generally favor or oppose the proposed settlement	40%	25%
Government should gradually ban the use of nicotine over a period of years until it is completely illegal	42%	52%
A ban on cigarette vending machines	67%	31%
A ban on outdoor advertising of cigarettes	60%	36%
A requirement that tobacco companies contribute money to provide health insurance to children who do not have insurance	63%	33%
A ban on tobacco companies sponsoring sports events or other live events	48%	48%
Limits on the ability of people who have smoking-related illnesses to sue the tobacco companies	48%	47%

Tobacco's deep roots in the economy

The tobacco industry contributes substantially to the U.S. economy. How much was added to the 1994 economy by the tobacco company, farm, supplier (makers of boxes, cellophane and other goods and services needed for tobacco products), people whose income came directly from a tobacco or advertising agency that works on tobacco accounts.

Tobacco is grown on more than 124,000 farms in 23 states and Puerto Rico. Top 10 tobacco-producing states in 1995, by cash receipts:

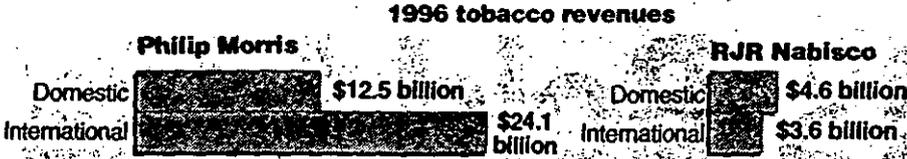


Contribution to gross domestic product: \$44.7 billion
Jobs: 1,662,402
Federal/state/local taxes: \$20.6 billion

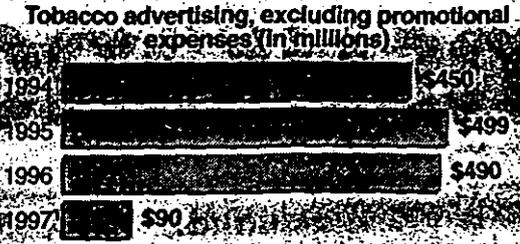


In the field: Workers harvest tobacco at a Maryland farm. In 1996, about 674,300 acres of tobacco were harvested in the USA — 1.32 billion pounds — down nearly 16% from 1994.

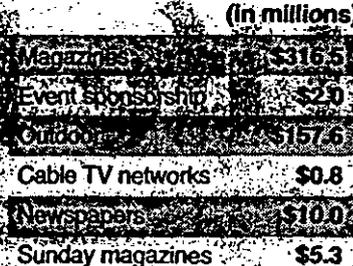
The USA's two biggest tobacco companies draw much of their tobacco revenue outside the USA



Tobacco companies are among Corporate America's leading advertisers



Where tobacco ad dollars go:



The average price for a pack of cigarettes in the USA is \$1.85. Average price by state, and how much of that cost is taxes:

State	Price	Tax
Washington	\$2.65	0.825
Massachusetts	\$2.45	0.770
Hawaii	\$2.43	0.600
Michigan	\$2.34	0.750
Dist. Columbia	\$2.30	0.650
New York	\$2.23	0.560
Arizona	\$2.22	0.580
Minnesota	\$2.17	0.480
Rhode Island	\$2.17	0.610
Alaska	\$2.14	0.290
Connecticut	\$2.09	0.500
Vermont	\$2.02	0.440
Wisconsin	\$2.01	0.440
California	\$2.00	0.370
Illinois	\$1.99	0.440
Nevada	\$1.99	0.350
Oregon	\$1.98	0.680
New Jersey	\$1.95	0.400
North Dakota	\$1.94	0.440
Maryland	\$1.91	0.360
Maine	\$1.90	0.370
Texas	\$1.90	0.410
Iowa	\$1.89	0.360
Utah	\$1.86	0.265
Nebraska	\$1.85	0.340
Idaho	\$1.84	0.280
Florida	\$1.83	0.339
South Dakota	\$1.82	0.330
Arkansas	\$1.81	0.310
New Hampshire	\$1.77	0.250
Pennsylvania	\$1.77	0.310
New Mexico	\$1.76	0.210
Colorado	\$1.74	0.200
Delaware	\$1.72	0.240
Oklahoma	\$1.72	0.230
Kansas	\$1.71	0.240
Mississippi	\$1.69	0.180
Alabama	\$1.67	0.165
Louisiana	\$1.67	0.200
Ohio	\$1.67	0.240
Wyoming	\$1.64	0.120
Montana	\$1.65	0.180
Missouri	\$1.63	0.170
Tennessee	\$1.61	0.130
West Virginia	\$1.61	0.170
Virginia	\$1.60	0.025
Georgia	\$1.59	0.120
Indiana	\$1.56	0.155
South Carolina	\$1.54	0.070
North Carolina	\$1.52	0.050
Kentucky	\$1.46	0.030

Sources: American Economic Group; Competitive Media Reporting and Publishers Information Bureau; The Tobacco Institute
USA TODAY research by Mary Cadden
1 - January to March
2 - Counties and cities may impose an additional tax
Additional distribution fees charged
By Marcy E. Mufins, USA TO

Tobacco - Settlement ~~to~~

July 1, 1997

NOTE TO BRUCE LINDSEY

FROM: Elizabeth Drye

SUBJECT: Tobacco Working Group Participants

Here are the current participant lists. We've only released the names of the chairs.

- I. **Regulatory Issues** (convened by Elena Kagan). This group will look at: (a) FDA regulation of product content, including nicotine; (b) FDA regulation of access, advertising, and labeling; and (c) 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.
- II. **Program and Budget Issues** (convened by Chris Jennings). This group will examine proposed uses of settlement funds, including programs to reduce smoking and expand children's health care coverage. In particular, the group will consider the use of settlement funds for: (a) children's health care; (b) education efforts (including grass roots programs); (c) smoking cessation programs; and (d) investments in health research, including nicotine research. White House offices are DPC, OMB, NEC, OVP, and OSTP. Participating agencies are HHS, Treasury, DOL, USDA, Interior, VA, and DOD.
- III. **Legal Issues** (convened by Elena Kagan). This group will review the settlement's provisions on liability, damages, and document disclosure, and will consider constitutional, antitrust, and other legal issues raised by the settlement. White House offices are DPC, OVP, NEC, and Counsel. Participating agencies are DOJ, HHS, Treasury, EPA, and Interior.
- IV. **Industry Performance and Accountability** (convened by Bruce Reed). This group will analyze the economic effects of a settlement. The group will assess: (a) the economics of the industry and the settlement's effects on industry performance, international markets, federal revenues, consumers, farmers, etc.; and (b) the set of incentives and penalties in the settlement to reduce tobacco use, especially by children. On a separate track, Dan Tarullo will oversee a look at Administration policy on tobacco-related trade and international issues, which the settlement does not directly address. White House offices are DPC, NEC, CEA, OVP, OMB, and OSTP; participating agencies are: HHS, Treasury, DOL, USDA, USTR, State, and DOD.

LEGAL ISSUES

CHAIR: Elena Kagan

Subject: Tobacco Liability/Litigation/Disclosure

	Attendees	
Bruce Reed	DPC	456-6515
Elizabeth Drye	DPC	456-5573
Jerry Mande	OSTP	456-6018
Ellen Seidman	NEC	456-2802
Charles Burson	OVP	456-7022
Andy Hyman	HHS	690-6318
Harriet Rabb	HHS	690-7741
Bill Schultz	FDA	301-827-3370
Mitch Zeller	FDA	301-827-3355
Patty Kaeding	FDA	301-827-1153
Margaret Porter	FDA	301-827-1137
Karen Schifter	FDA	301-827-1148
Michael Eriksen	CDC	770-488-5701
George Phillips	DOJ	514-5713
John Dwyer	DOJ	514-9500
Gene Thirof	DOJ	307-0066
Jonathan Gruber	Treasury	622-0090
Neal Wolin	Treasury	622-0283
Eleni Constantine	Treasury	622-1934
Gary Guzy	EPA	260-7960
Robert Dreher	EPA	260-

8040

REGULATORY ISSUES

CHAIR: Elena Kagan

Subject: FDA Rule & Environmental Smoke

	Attendees	
Bruce Reed	DPC	456-6515
Elizabeth Drye	DPC	456-5573
Jerry Mande	OSTP	456-6018
Ellen Seidman	NEC	456-2802
Toby Donenfeld	OVP	456-6265
Don Arbuckle	OMB	395-5897
Jim Esquea	OMB	395-4926
Wendy Taylor	OMB	395-6974
Michael Fitzpatrick	OMB	395-1247
Andy Hyman	HHS	690-6318
Harriet Rabb	HHS	690-7741
Bill Schultz	FDA	301-827-3370
Mitch Zeller	FDA	301-827-3355
Patricia Kaeding	FDA	301-827-1153
Lee Wilson	SAMHSA	301-443-6085
Michael Eriksen	CDC	770-488-5701
George Phillips	DOJ	514-5713
John Dwyer	DOJ	514-9500
Gene Thirof	DOJ	307-0066
Tony Sutin	DOJ	514-8950
Richard Shiffrin	DOJ	514-2046
Jennifer O'Connor	Labor	219-6197
Emily Sheketoff	Labor	219-6104
Neal Wolin	Treasury	622-0283

Regulatory Subgroup A

Subject: Advertising/Access/Labeling/Enforcement

Attendees

Elena Kagan	DPC	456-5565
Elizabeth Drye	DPC	456-5573
Jerry Mande	OSTP	456-6018
Charles Burson	OVP	456-7022
Toby Donenfeld	OVP	456-6265
Don Arbuckle	OMB	395-5897
Michael Fitzpatrick	OMB	395-1247
Andy Hyman	HHS	690-6318
Bill Schultz	FDA	301-827-3370
Mitch Zeller	FDA	301-827-3355
Patricia Kaeding	FDA	301-827-1153
Judith Wilkenfeld	FDA	301-827-0933
Sharon Natanblut	FDA	301-827-3442
Lee Wilson	SAMHSA	301-443-6085
George Phillips	DOJ	514-5713
Gene Thirof	DOJ	307-0066
Tony Sutin	DOJ	514-8950
Randy Moss	DOJ	514-3745
Doug Letter	DOJ	514-3602
Michael Raab	DOJ	514-4053
Neal Wolin	Treasury	622-0283
Steve McHale	Treasury	927-7772
John Simpson	Treasury	622-1426
Eleni Constantine	Treasury	622-1934
Jennifer O'Connor	Labor	219-6197

Regulatory Subgroup B

Subject: FDA Product Regulation Content & Safety

Attendees

Elena Kagan	DPC	456-5565
Elizabeth Drye	DPC	456-5573
Jerry Mande	OSTP	456-6018
Charles Burson	OVP	456-7022
Toby Donenfeld	OVP	456-6265
Don Arbuckle	OMB	395-5897
Michael Fitzpatrick	OMB	395-1247
Andy Hyman	HHS	690-6318
Bill Schultz	FDA	301-827-3370
Mitch Zeller	FDA	301-827-3355
Patricia Kaeding	FDA	301-827-1153
Ann Witt	FDA	301-827-3360
Catherine Lorraine	FDA	301-827-3360
Michael Eriksen	CDC	770-488-5701
George Phillips	DOJ	514-5713
Gene Thirof	DOJ	307-0066
Tony Sutin	DOJ	514-8950
Jennifer O'Connor	Labor	219-6197
Gary Christoperson	DOD	703-697-2111
John Mateczun	DOD	703-695-4964
Lynn Pahland	DOD	703-695-2640

Regulatory Subgroup C

Subject: Environmental Tobacco Smoke

Attendees

Elena Kagan	DPC	456-5565
Elizabeth Drye	DPC	456-5573
Jerry Mande	OSTP	456-6018
Wendy Taylor	OMB	395-6974
Debra Bond	OMB	395-7361
Andy Hyman	HHS	690-6318
Rip Forbes	HHS	260-2255
Michael Eriksen	CDC	770-488-5701
Mary Smith	EPA	233-9370
Jennifer O'Connor	Labor	219-6197
Emily Sheketoff	Labor	219-6104
Gary Christoperson	DOD	703-697-2111
Stanley Lanfeld	GSA	501-1731

TOBACCO BUDGET GROUP LIST

Chair: Chris Jennings

Name	Office	Phone	Fax
Emily Bromberg	White House	456-2896	456-2889
Elizabeth Drye	White House	456-5573	456-7431
Rahm Emanuel	White House	456-2530 (Michelle)	456-2530
John Hilley	White House	456-2230 (Elisa)	456-
Chris Jennings	White House	456-5560	456-5557
Elena Kagan	White House	456-5584 (Laura)	456-2878
Jeanne Lambrew	White House	456-5377	456-7431
Bruce Reed	White House	456-6515	456-2878
Gene Sperling	White House	456-	456-
Dan Tate	White House	456-6620	
Barbara Woolley	White House	456-2155	
Don Gips	OVP	456-6222	456-6231
Toby Donenfeld	OVP	456-6265	456-6231
Mark Mazur	CEA	395-5147	395-6958
Sarah Reber	CEA	395-5618	
Rich Tarplin	HHS	690-7627	690-7380
Gary Claxton	HHS	690-6870	401-7321
Bruce Vladeck	HHS	690-6726	690-6262
Nancy-Ann Min	OMB/HHS	395-5178	395-7289
Josh Gotbaum	OMB	395-3060	395-3174
Jerry Mande	OSTP	456-6018	456-6207
Jennifer O'Connor	Labor	219-6197	219-9216
Jonathan Gruber	Treasury	622-0090	622-2633
Larry Summers	Treasury	622-1080	622-0081
Ramona Trovato	EPA	260-7778	260-4103
Charles Rawls	USDA	720-6158	720-5437

Industry Performance and Accountability

CHAIR: Bruce Reed

Name	Agency	Phone	Fax
Janet Yellen	CEA	395-5042	-6958
Jennifer Haverkamp	USTR	395-7320	-4579
Peter Soher	USTR	395-5057	-3390
Larry Braslow	FDA	301-827-5331	-5340
Judith Wilkenfeld	FDA	301-827-5321	-443-5169
Harriet Rabb	HHS/OGC	690-7741	-7998
Michael Eriksen	CDC/HHS	770-488-5701	-5767
Andy Hyman	HHS/OGC	690-6318	-7998
Josh Gotbaum	OMB	395-3060	-3174
Joe Minarik	OMB	395-5873	-1198
Ed Montgomery	DOL	219-5108	-4902
Jennifer O'Connor	DOL	219-6197	-9216
Jerry Mande	OSTP	456-6018	-6027
Larry Summers	Treasury	622-5300	
Steve Wandner	DOL	219-5677 x157	-5455
Mark Mazur	DPC/CEA	395-5147	-6809Toby
Toby Donenfeld	OVP	456-6265	-6231
Wendy Taylor	OMB	395-7316	-6974
Ellen Seidman	NEC	456-5359	-1605
Jon Gruber	Treasury	622-0563	-2633
Peter Orstay	NRC	456-5358	-2223
Chad Stone	CEA	395-5086	-6958
Joe Glauber	USDA	720-6185	
Charlie Rawls	USDA	720-6158	-5437
Don Arbuckle	OMB	395-5897	-7245
Paul Weinstein	DPC	456-5577	-7028
Elizabeth Drye	DPC	456-5573	-7028
Dan Tarollo	WH	456-5353	
Alicia Munnell	CEA	395-5036	

INDUSTRY PERFORMANCE SUBGROUP A
 Issues: economic analysis/incentives/performance penalties

<u>NAME</u>	<u>AGENCY</u>	<u>PHONE</u>	<u>FAX</u>	<u>E-mail</u>
Don Arbuckle	OMB	(202) 395-5897	(202) 395-7245	
Larry Braslow	FDA	(301) 827-5331	(301) 827-5340	lbraslow@fda.gov
Jonathan Gruber	Treasury	(202) 622-0563	(202) 622-2633	jonathan.gruber@treas.spring.com
Karen Hendershot	Treasury	(202) 622-1683	(202) 622-2563	karen.hendershot@treas.sprint.com
Susan Lepper	Treasury	(202) 622-1761	622-2358 (3)	susan.lepper.treas.sprint.com
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Jerry Mande	OSTP	(202) 456-6018	(202) 456-6027	
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Judy Wilkenfeld	FDA	(301) 827-5321	(301) 443-5169	

Industry Performance Subgroup B
Issues: International

<u>Agency</u>	<u>Name</u>	<u>Phone #</u>	<u>Fax #</u>
CEA	Chad Stone	395-5086	395-6958
CEA	Carrie Thompson	395-3517	
DPC	Elizabeth Drye	456-5573	456-7028
DPC	Paul Weinstein	456-5577	456-7028
OSTP	Jerry Mande	456-6018	456-6027
HHS	Andy Hyman	690-6318	690-7998
HHS/CDC	Michael Eriksen	205-9221	205-8313
USTR	Jennifer Haverkamp	395-7320	395-4579
State/OES	Nancy Carter-Foster	647-2435	736-7336
State/EB	Amy Winton	647-1490	647-1894
OMB	Joe Minarik	395-5873	395-1198
USDA	Charlie Rawls	720-6158	720-5437
USDOC	J. Hayden Boyd	482-0337	482-3981
Labor	Jennifer O'Connor	219-6197	219-9216
EPA	David Berman	260-8138	260-0279
Treasury/OASIA	Meg Lundsager	622-0168	622-5304
Ex-Im Bank	James Cruse	565-3761	565-3770
OPIC	Harvey Himberg	336-8614	408-5145

Name	Date
<i>Karl Racine</i>	<i>4/5/2000</i>

Counsel

Notes for
big ref
mts

Worst - vent scrub - 30 days
30 days

Tobacco - settlement -
~~regulatory group~~

sometimes get together in subgroups

(Tuesday)

1. FDA ~~jurisdiction~~ regulation of product 13-20; ~~BLA/ADA~~ HHS/FDA // DOJ

a. Basic concept/structure
i.e. limited time for grad. reduction / then elim.

b. "Fine" points - burden of proof, std of proof, substantive showings
(Pres), procedural rules

c. Other - e.g. non-tobacco ingredients ~~regulatory authority~~ ³²⁻³³ ~~23-24~~

HHS/FDA
(Monday)

2. Access, Advertising, Labelling 8-13; 43-45 (Apps I-III); 43 (App VII)

In general: assume we agree w/ everything in rule; do we agree
w/ everything else; do we want more (use your imagination)

- a. Access (~~marketing~~) 11-13; App 2
- b. Advert 8-9; App 7
- c. Labelling 9-11

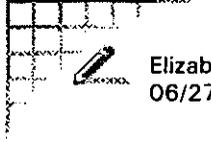
3. ETS 30-32 DOL (OHA) (Monday)

Scrub this: anything we don't want? can't call today
anything else we do?

(Legal)

Preemption rules - DOT - ~~scope of authority~~
Antitrust scrub - DOT

licensing to legal



Elizabeth R. Newman
06/27/97 11:40:14 AM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP

cc:

Subject: Final Tobacco Paper from HHS

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). Where appropriate, each 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.

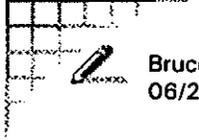
President Clinton's Plan to Reduce Youth Tobacco Use

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.

Tobacco -
settlement



Bruce N. Reed
06/23/97 02:07:58 PM

Record Type: Record

To: Joseph P. Lockhart/WHO/EOP
cc: See the distribution list at the bottom of this message
Subject: Tobacco Process Talking Points

Here are the points on our tobacco process that Barry can make at today's briefing:

- Today, we have begun our review of the proposed tobacco settlement.
- The review will involve several agencies (HHS/FDA, DOJ, Treasury, USDA, DOL, OMB, etc.) as well as several WH offices (DPC, NEC, CEA, etc). We have established working groups on the major issues in the settlement. The main groups to highlight for press consumption are on 1) FDA regulation/marketing/access/labeling; 2) Budget issues (how the money is spent); and 3) Industry analysis (which will look at incentives in the agreement, the industry's financial picture, etc.). Other groups include workplace smoking; smoking cessation; litigation/liability/disclosure; international issues; and implementation issues. The budget and litigation groups met today.
- The President has given us a timeline of 30 days (in his news conference yesterday).
- Over the next few weeks, we will be reviewing the terms of the settlement, with a particular focus (as the President said yesterday) on the FDA piece and the budget piece. We will reserve judgment on individual provisions until we can assess the overall agreement.
- Over that time, we will also meet with leaders in the public health community, including the major public health organizations, Drs. Koop and Kessler, leading tobacco foes on the Hill, etc.
- The review will look at the question of what we can accomplish with a settlement and without one, as well as assessing what is good, what is insufficient, and what may be missing or unclear with respect to this particular settlement.
- **As the President said yesterday, we view this as a great opportunity to advance the public health. 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. It will take us some time to make a serious, informed judgment on the terms of this settlement, but we are delighted that our actions and the steadfast efforts of the attorneys general have changed the landscape on tobacco for all time.**

Message Copied To:

Elena Kagan/OPD/EOP
Elizabeth Drye/OPD/EOP
Jerold R. Mande/OSTP/EOP
Christopher C. Jennings/OPD/EOP
Sarah A. Bianchi/OMB/EOP
Jeanne Lambrew/OPD/EOP

Tobacco - settlement

Eliz - live written
in the back of a
envelope of paper.

June 26, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Tobacco Settlement Review Process

This memo sets forth the process we will use to ~~review and~~ evaluate the proposed tobacco settlement ~~with relevant agencies, to seek input from the public health community, Congress, and others,~~ and to present recommendations to the President. Our goal is to prepare a memo for the President by late July that defines our public health and public interest objectives ~~for a global settlement;~~ weighs the settlement's strengths and weaknesses against those objectives ~~and proposes possible modifications;~~ summarizes the views of the public health community, Congress, and other affected parties; and lays out positions the President could take on the settlement proposal.

Interagency Review

The review will be carried out by four major workgroups,

which have already begun meeting this week *have begun to meet:*

I. **Regulatory Issues** (Chaired by Elena Kagan). ~~Subgroups~~ *This group/* will look at: (a) FDA regulation of product content; (b) FDA regulation of access, advertising, and labeling; and (c) restrictions on environmental tobacco smoke in public buildings and workplace settings. Participating White House offices are DPC, OMB, OVP, NEC, OSTP. Participating agencies are HHS, DOJ, DOL, GSA, EPA, Treasury.

and including nicotine and

II. **Program and Budget Issues** (Chaired by Chris Jennings). This group will examine programs to reduce smoking, expand children's health care coverage, ~~and other proposed uses of settlement funds.~~ Subgroups will consider: (a) ~~Medicaid funds~~ children's health care; (b) education efforts (including grass roots programs); (c) smoking cessation programs; and (d) investments in health research, including nicotine research. White House offices are DPC, OMB, NEC, OVP, OSTP. Participating agencies are HHS, Treasury, DOL, USDA, Interior, VA, and DOD.

In particular, the group

III. **Legal Issues** (Chaired by Elena Kagan). This group will ~~consider a number of~~ *review the settlement's provisions* legal issues, including liability, litigation, document disclosure, and antitrust questions. White House offices are DPC, OVP, NEC, Counsel. Participating agencies are DOJ, HHS, Treasury, Interior.

SEE OVER

proposed uses of settlement funds, including

and the use of Medicaid funds for

on liability, damages, and document disclosure, and will consider constitutional, antitrust, and other legal issues raised by the settlement.

IV. **Industry Performance and Accountability** (chaired by Bruce Reed). This group will analyze economic and international issues. Subgroups will assess: (a) the economics of the industry and the settlement's effects on industry performance, federal revenues, consumers, farmers, etc.; ^{and} (b) the incentives and penalties industry would face if children's tobacco use exceeds targets; and (c) Administration policy on tobacco-related trade and international issues, ^{which does not directly involve the settlement.} and the settlement's international implications. White House offices are DPC, NEC, CEA, OVP, OMB, OSTP; participating agencies are: HHS, Treasury, DOL, USDA, USTR, State, DOD.

Kevin will argue over this

in particular, the group

SEE OVER

Public Outreach

and Paul

does not directly address.

We will work with OPL and HHS ^{on} to run a tightly focused public outreach effort designed to demonstrate ^{that} the President is conducting a thoughtful, thorough review focused on the public health. Many groups covering a wide range of interests are affected by the proposed settlement. We will narrow our task ^{and reinforce the} President's focus on public health ^{emphasize} by hosting 6-8 highly visible White House meetings with small, select groups of health experts. We will encourage others to share their views through written comments and, where appropriate, meetings with agency staff.

~~with health experts~~

Donna and I will host the White House meetings over the next three weeks. We will convene ~~leading thinkers on tobacco, including~~ experts from national health organizations; Koop-Kessler advisory group participants; experts on nicotine addiction; local grass-roots advocates; state and local tobacco control officials; and children's health advocates.

The first meeting will ~~be~~ ^{take place} on Friday. We will invite in Dr. Kessler and several members of the Koop-Kessler advisory group, including the American Cancer Society, American Medical Association, and the American Lung Association. (Koop is not available.) The committee will not have finished its report, but will be able to ^{it can} validate ~~the careful, thorough review, the Administration is conducting~~ and praise the President for expressing concern over the proposal's handling of nicotine regulation. ^{realize this week}

Congressional Outreach

the Administration's review process

-- this is a placeholder based on my conversation with Rich this morning. Rich is seeing if he can put off Lautenberg meeting until week after next.

If the ^{Admin. decides} ~~President chooses~~ to ^{support some kind of} ~~promote~~ a settlement, ^{we} he will need strong and broad Congressional support. Multiple committees in both the House and Senate would have jurisdiction over legislation enacting an agreement. The goal of our Congressional outreach process will be to strengthen relationships on the issue with key members, keeping the debate bipartisan. Today and tomorrow HHS is making

and to

(b) the set of incentives and penalties in the settlement
to reduce tobacco use, especially by children

calls to key Republican and Democratic members to ~~let~~ seek their input on how best to consult with the Hill in the coming weeks. We ~~expect to conduct meetings with members the week of July 7, and will have a more detailed outreach plan by mid-week next week.~~ ^{are working with} ~~members~~ with Legal Affairs and HHS on a ^{list of} ~~more detailed~~ Congressional meetings ^{to begin the week of July 7.}

Press Plan

This issue is certain to attract considerable press attention throughout our review. Major news organizations have assigned entire teams to cover the tobacco settlement. After devoting so much coverage to the negotiations, the networks are determined to keep this issue alive. We should take advantage of that heightened interest to advance our public health message.

On Friday, Donna and I are prepared to brief the White House press corps on how we will conduct this review, who will be involved from within the administration, and what groups and outside experts we plan to consult. As noted above, on Friday we will also invite David Kessler and other members of the Koop-Kessler advisory group to discuss their efforts ~~to develop an expanded blueprint on tobacco control.~~

^{During} (The week of July 7, while the President is away, Donna and I will conduct the public health and Congressional meetings described above. This will give the press something to write about, and show that we're running an open process. ^{will meet with} The week of July 14, we will continue public health and Congressional meetings and bring in two groups of attorneys general -- the enthusiasts and the skeptics. The Vice President is willing to hold a public hearing with us in mid-July ^{are} ~~(Bruce let's talk about this -- there are downsides.)~~ ^{During} if we need one. (We prefer to leave this question open right now.)

^{But we} Schedule We have planned the following schedule. HHS does not believe the review can be completed within 30 days, as the President suggested. We will work as quickly as possible to preserve that option ^{and} but ensure a decision by early August at the latest.

Week of June 23: analytic tasks.	Work groups convened ^{members} subgroups assigned
June 27: process.	Donna and Bruce brief press in process and conduct first outreach meeting and press briefing on
Week of June 30: key remaining issues.	Groups/ Subgroups provide preliminary assessments/ define of
Week of July 7: and synthesize work	Groups/ Subgroups develop options for outstanding issues ^{key/}

Continue White House meetings with public health groups and Begin meetings with members of Congress.
Donna, Bruce, and others had further
DPC convenes work groups and assigns analytic tasks to members.
Eliz - name of these the week of June 30?

Week of July 14:	Principals review workgroup assessments and meet
to firm up options.	
discuss	Possible public hearing with VP the Vice Pres.
Week of July 21:	Initial meeting with the President
late July/early Aug:	Presidential decision <i>and announcement</i>

^{ust}
_^
 ↖
 ↙

Eliz-

We should list members of Congress + health experts to the extent we can.

Good job.

Eliz

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.

Tobacco -
supplement



DEPARTMENT OF HEALTH & HUMAN SERVICES

Melissa T. Skolfield

Assistant Secretary for Public Affairs

Phone: (202) 690-7850 Fax: (202) 690-5673

To: Elena Kagan

Fax: 456-2878 Phone: 456-5582

Date: 6/26 Total number of pages sent: 6

Comments:

Elena-

Here are draft Q+As on the tobacco review process. Bruce has not cleared the 1st two pages, but has signed off on the rest.

Pls. let melissa or Ioly know if you have comments/questions.

Thanks,

DRAFT - Bruce has not signed off on these.

Q: How exactly is this process going to work?

A: We have decided to do our preliminary analysis by setting up four interdepartmental review panels. Each will include a member of the DPC and at least one representative of HHS. All panels will also have representatives of other departments, such as Treasury, Justice, Labor, as the subject matter suggests.

The four areas the panels will explore are regulatory issues, program and budget issues, legal issues, and industry issues.

The regulatory panel will primarily be sorting through the elements in the proposed settlement affecting FDA jurisdiction. It will also look at issues surrounding environmental tobacco smoke. In addition to HHS and the DPC, the Department of Labor and the EPA will be represented on this panel.

The program and budget panel will be looking at issues surrounding children's tobacco use, the proposed anti-smoking campaign, the proposed funding for smoking cessation, and any issues that involve research to date on smoking and tobacco, including smoking cessation. This panel will also be looking at the interaction between the funding for children's health insurance contained in the budget reconciliation legislation and the additional funding proposed in the settlement.

The legal panel will be examining issues around liability, enforcement, compliance, and the disposition of tobacco industry documents. In addition to DPC and HHS staff, it will include representatives from a number of units within the department of Justice.

The industry issues panel will be examining the settlement's proposed targets, penalties and incentives; looking at any international impacts of the settlement; and doing an economic analysis. In addition to representatives of the DPC and HHS, the Treasury Department and the Council of Economic Advisors (CEA) will be represented on this panel.

Q: Will this be the structure for the entire review period? Will each of these panels produce a report?

A: This process is our first cut at a framework for what is a very complicated legal and policy review. Over time, as we move from analysis of the individual issues to a process of synthesizing the issues and looking at the proposed settlement as a whole, the process may shift slightly.

It is unlikely that the panels will produce written reports. We will, however, try to lay out the issues for the President near the end of the process.

- Q: What do you mean by an economic analysis? Do you mean trying to find out if the tobacco industry is being "punished" enough, as some have suggested?
- A: It is our intention to see how the settlement would differ from the President's own proposal in this respect. We want to understand the effects on the U.S. economy of what the proposed agreement calls, "restructuring the tobacco industry."
- 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 Elena Kagan.
- Q: Will Bruce Lindsey play a role?
- A: [Needed from White House]
- Q: Have any of these panels met?
- A: All of them have met at least once.
- Q: Are the HHS representatives all from FDA?
- A: No. Because of the complexity of the proposed settlement, the HHS team also includes representatives from the Office of the General Council, the National Institutes of Health, and the Centers for Disease Control and Prevention.

Bruce has cleared these

DRAFT - CLOSE HOLD

Questions and Answers on Review Process of Tobacco Proposed Settlement

Q How long will the Administration's review of the proposed settlement take?

A We're moving expeditiously, but you have to understand that this is a very complex undertaking. We need to have a thorough understanding not only of all the individual parts of this proposal, but also of how those parts interact with one another.

Q But didn't President Clinton ask for a report within 30 days?

A Well, we certainly expect to meet with within approximately 30 days to lay out for him the major issues our review has identified. But again, this is a very complex undertaking, and while we'll be moving forward with vigor, we're going to take as long as we need to get the job done right.

Q Why will the review take so long?

A This is an extremely complicated issue that has critical legal and public health ramifications for our children and our nation. Don't forget it took the parties involved in the negotiations four months to reach this proposed settlement. And it took the Department of Health and Human Services 12 months to draft and finalize the historic FDA final rule to protect children from the dangers of tobacco.

We must take apart the proposed settlement and carefully review every angle, and we must also determine whether the proposed deal as a whole advances the nation's public health interests and the progress we've already made to keep tobacco out of the hands of children. We intend to work expeditiously, but will not leave any stone unturned to ensure a good deal, not just on its own terms, but most importantly for the American people.

Q Why is it so complicated?

A There are a number of complex legal and public health issues related to the proposed settlement. For example, the Food and Drug Administration's jurisdiction over tobacco involves very complicated and important legal issues. With the President's leadership and the concrete steps the Food and Drug Administration already has taken, we are making progress in keeping tobacco out of the hands of children. But we want to continue with our lawsuit to make sure that the FDA rule stands. We do not want to do anything to jeopardize our court case. As the President has said, it is critical to protect our children by standing firm in our determination to ban the advertising and marketing of cigarettes that endanger their lives. That is why we must carefully review the part of the agreement that relates to the jurisdiction of the FDA.

This is also a critical public health issue. 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. We cannot support any agreement unless it meets this high standard set by the President – because no less than our children's futures are at stake.

Q But some people are already criticizing the proposed agreement, saying that it is deeply flawed and will need to be changed significantly. How do you respond?

A This massive agreement was only reached last week so we have not yet had enough time to carefully review all of the complex legal and public health issues that the proposed settlement raises. Over the next several weeks we will take the agreement apart and examine every angle, and we also must determine whether the proposed deal as a whole advances the nation's public health interests and the progress we already have made in keeping tobacco out of the hands of our children.

We will consider closely the views of the public health community, all interested agencies, members of Congress and others before rendering any judgment on the proposed settlement. We will work expeditiously, but will not leave any stone unturned to ensure a good deal, not just on its own terms, but most importantly for the American people.

Q Today the public health community attacked the proposed agreement saying that the future restrictions on the government to regulate nicotine are unacceptable. Do you agree?

A Again, this massive agreement was only reached on Friday so we have not yet had enough time to carefully review all of the complex legal and public health issues that the proposed settlement raises. We will conduct a rigorous review of each piece of the agreement, but we must determine whether the agreement as a whole represents the best means of protecting the nation's public health interests. And we will consider closely the views of the public health community, all interested agencies, members of Congress and others before rendering any judgment on the proposed settlement.

But remember that this agreement was built in large measure on the President's bold leadership and the concrete steps the FDA already has taken to keep tobacco out of the hands of children. Last year's historic FDA rule to protect children from the harm caused by tobacco products and the recent landmark ruling upholding that rule in a North Carolina court, drove the tobacco companies to the bargaining table and extracted concessions from them that would have been unimaginable just a short time ago. We are keeping an open mind as we carefully review all of the complex legal and public health issues raised in the proposed settlement -- including the issues relating to the jurisdiction of the FDA -- but we will not back away from our commitment to protecting children and the public health. We will not support any agreement unless it meets the high standard set by the President.

Q But what do you think of Koop/Kessler group's discussion that the deal is "unacceptable?" Aren't their views the ones that will guide the President's decision?

A As we begin our own rigorous public health review, we appreciate the contribution of Doctors Koop and Kessler and the Advisory Committee on Tobacco Policy and Public Health. We look forward to working with the public health community and others to determine whether the proposed settlement upholds the President's highest objectives of protecting our children and the public health.

The proposed settlement raises numerous complex legal and public health issues that we will work conscientiously and expeditiously to review over the next several weeks. We will look closely at every angle to evaluate whether the proposed agreement as a whole advances the nation's public health interests, especially our children's health.

DRAFT

We have not yet had a chance to review the tobacco settlement, and we have reached no decision on whether it serves the public health. We are now engaged in an extensive interagency process, including consultation with outside experts, to decide whether the complete terms of the agreement will protect the public health -- and especially our children's health. We will be particularly attentive to the piece of the settlement agreement dealing with FDA jurisdiction, to ensure that the FDA has all necessary authority to regulate nicotine and tobacco products.

We will not, however, reject the settlement agreement simply because it limits punitive damage awards against tobacco companies for their past misconduct. If the settlement as a whole is in the interest of the public health, the inability of smokers and their lawyers to receive damages over and above their actual losses will not keep us from supporting the agreement. The key question is not whether the settlement allows litigants to recover punitive damages for past misconduct, but whether the settlement advances the President's goal of keeping children safe from the harm of tobacco products. *ad. administrative plaintiffs*

*not a
doubtless*

Brag on POTUS

Punitive fund

Tobacco - settlement

THE WHITE HOUSE
WASHINGTON

MEMORANDUM FOR ERSKINE BOWLES
RAHM EMANUEL
RON KLAIN
MIKE McCURRY

FROM: ELENA KAGAN

SUBJECT: TOBACCO STATEMENT

Attached is a new draft, reflecting this morning's conversation. Bruce Reed and Bruce Lindsey have seen it.

DRAFT

We have not yet had a chance to review the tobacco settlement, and we have reached no decision on whether it serves the public health. We are now engaged in an extensive interagency process, including consultation with outside experts, to decide whether the complete terms of the agreement will protect the public health -- and especially our children's health. We will be particularly attentive to the piece of the settlement agreement dealing with FDA jurisdiction, to ensure that the FDA has all necessary authority to regulate nicotine and tobacco products.

We will not, however, reject the settlement agreement simply because it limits punitive damage awards against tobacco companies for their past misconduct. If the settlement as a whole is in the interest of the public health, the inability of smokers and their lawyers to receive damages over and above their actual losses will not keep us from supporting the agreement. The key question is not whether the settlement allows litigants to recover punitive damages for past misconduct, but whether the settlement advances the President's goal of keeping children safe from the harm of tobacco products.