

THE WHITE HOUSE  
WASHINGTON

*DPC Meeting Agenda*  
*August 7, 1997*

1. Public Health Issues
  - FDA Jurisdiction
  - Advertising Ban
  - Environmental Tobacco Smoke
2. Legal Issues
3. Budget Issues
4. Youth Smoking Penalties
5. Growers
6. International

## CLINTON ADMINISTRATION OUTLINES TOBACCO SETTLEMENT REVIEW PROCESS

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### 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.

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

## **Question and Answer on Tobacco Settlement Proposal Review Process**

June 27, 1997

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

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

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

(more detailed descriptions of groups below)

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

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

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

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

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

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

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

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

**Q. Who will lead the HHS team?**

A. Secretary Shalala and Deputy Secretary Kevin Thurm.

**Q. Who will lead the DPC team?**

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

**Q. Have any of the panels met?**

A. All of them have met at least once.

**Q. Why will this take so long?**

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

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

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

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

**A.** TBD

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

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

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

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

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



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Jerold R. Mande

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Record Type: Record

To: Elizabeth Drye/OPD/EOP

cc:

Subject: Tobacco

A Talk With Clinton's Point Man On Tobacco

Business Week Online Q&A

Friday, June 27, 1997

Edited by Richard S. Dunham

President Clinton recently named White House Domestic Policy Counsel director Bruce N. Reed and Health & Human Services Secretary Donna Shalala to head the Administration's review of the recent tobacco settlement (see BW, 7/7/97, "The Tobacco Deal: Not So Fast"). On June 24, Reed discussed their mission with Business Week White House Correspondent Richard S. Dunham. Here are excerpts of their conversation:

Q: What do you hope to accomplish during your review of the tobacco deal?

A: Our review needs to answer two basic questions: Can we accomplish our public-health goals better with some kind of settlement or without one? And second, is this the right settlement?

Q: Many public-health advocates have been critical of the settlement. Do you have any particular concerns about it?

A: We are going to look closely at every aspect [of the deal]. The key questions include the FDA's ability to do its job, the overall financial terms of the settlement and what the money goes for, and a handful of legal and practical issues about how an agreement like this would work if it would go forward. We also will look at the performance measures in the package to make sure [the number of] children smoking is actually reduced.

Q: You may be able to assess the monetary benefits of a settlement. But how do you assess the situation if the deal breaks down and you have ongoing litigation over FDA jurisdiction, a series of state trials, and possible congressional action?

A: It's more difficult to assess the world without a settlement.

Q: Which way is the Administration leaning: Toward approving a settlement with modifications or opposing it entirely?

A: It's too early to tell.

Q: Do you think the Administration will end up on the same side as the majority of public-health advocates and congressional activists?

A: It's way too early to predict. We all go into this with the same objective. We're all approaching it from the same side.

Q: And what's that objective?

A: We see the debate over this settlement as an enormous opportunity to advance the public health, one way or another. It gives us a chance to build on the progress we made in the first four years [of the Clinton Presidency] with regard to [reducing] children's smoking. We're determined to make sure that something good comes out of this whole effort.

Q: How will you proceed during your monthlong review process?

A: We want to conduct a thorough review. We will reach out to all the experts. We've already had conversations with many of the leaders of the public-health community, [Former FDA Director] Dr. [David] Kessler, [Former Surgeon General] Dr. [C. Everett] Koop, [child-smoking advocate] Matt Myers, and others. We've been in contact with various organizations across the public-health community and key members of Congress. We have a team within the Administration of experts who will be looking at all the various elements of the settlement. We will widen that net, too, to include half a dozen [federal] agencies and several White House offices. We want to cast as broad a net as possible.

Q: Does that net include tobacco industry officials or lobbyists such as former Texas Governor Ann Richards?

A: I have not had any conversations with tobacco representatives, apart from briefings with negotiators along the way. The industry views are reflected in the settlement. We've turned it over to the rest of the world to look it over.

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**DRAFTS**

Week of July 7<sup>th</sup>

June 26, 1997

HHS  
Memo to Effman  
copies for  
Rahn, Sylvia  
John  
Elena  
Maria E  
✓

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 a ~~memo~~ <sup>analysis</sup> 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** (<sup>convened</sup> ~~chaired~~ 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** (<sup>convened</sup> ~~chaired~~ 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: <sup>Medicaid</sup> ~~(a) the use of~~ <sup>Medicaid</sup> funds for 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** (<sup>convened</sup> ~~chaired~~ 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, and Interior. <sup>EPA</sup> \*
- IV. **Industry Performance and Accountability** (<sup>convened</sup> ~~chaired~~ by Bruce Reed). This group will analyze economic and international issues. The group will assess: (a) the economics of the industry and the settlement's effects on industry performance, federal revenues, consumers, farmers, etc.; and (b) the set of incentives and penalties in the settlement to reduce tobacco use, especially by children. <sup>effects of a settlement</sup> ~~The group also will consider~~ Administration <sup>international markets</sup> \*

On a separate track, Dan Tarullo will oversee a look at

~~policy on tobacco-related trade and international issues, which the settlement does not directly address.~~ White House offices are DPC, NEC, CEA, OVP, OMB, OSTP; participating agencies are: HHS, Treasury, DOL, USDA, USTR, State, DOD.

(HHS - line on internal)

## 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 the public health.~~ 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. ~~We will encourage others to share their views through written comments and, where appropriate, meetings with agency staff.~~

*issues and to emphasize the President's focus on these issues.*

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 nicotine addiction; local grass-roots advocates; state and local tobacco control officials; and children's health advocates.

~~The first meeting will take place on [Monday, June 30].~~ We will invite in Dr. Kessler and several members of the Koop-Kessler advisory group, including the American Cancer Society, American Medical Association, and American Heart Association. (Koop is not available.) The committee will not have finished its report, but it can validate the Administration's review process and praise the President for expressing concern earlier this week over the proposal's handling of nicotine regulation. 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.*  
~~If the Administration decides to support some kind of settlement, we will need 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 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.

## 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.

*We will encourage other interest groups (children's advocates, women's organizing farmers) to share their views*

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 [Monday] we will meet with David Kessler and other members of the Koop-Kessler advisory group to discuss their efforts.

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. ~~(We prefer to leave this question open right now.)~~

### Schedule

We have planned the following schedule. <sup>Some</sup> ~~HHS does 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: DC 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.  
~~[First outreach meeting.]~~
- Week of July 7: Groups develop options for key issues.  
Bruce, Donna and others hold further 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.  
Possible public hearing with the Vice President.
- Week of July 21: Initial meeting with the President.
- Late July/  
early August: Presidential decision and announcement.

Eliz- live written  
in the back of a  
cuple of pages.

proposed uses of settlement funds including

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

*On a separate track, another subgroup will take at*  
*The group also will consider*

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.; *in particular, the pump* (b) the incentives and penalties industry would face if children's tobacco use exceeds targets; *SEE OGR* and (c) Administration policy on tobacco-related trade and international issues, *which would not directly involve the settlement*. White House offices are DPC, NEC, CEA, OVP, OMB, OSTP; participating agencies are: HHS, Treasury, DOL, USDA, USTR, State, DOD.

#### Public Outreach

*Kevin will argue over this*

We will work with OPL and HHS *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 *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. *emphasize*

*with the settlement*

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.

*take place*

The first meeting will *be* 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* validate the careful, thorough review the Administration is conducting, and praise the President for expressing concern over the proposal's handling of nicotine regulation. *it can*

#### 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.

*Admin. decides* *support some kind of* *we*

If the ~~President chooses~~ *to promote* a settlement, *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.~~ <sup>are working with</sup> ~~are working with~~ <sup>legis. Affairs and HHS on a</sup> ~~list of~~ <sup>to begin the week of July 7.</sup> ~~more detailed Congressional meetings~~

## 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~~ <sup>will meet with</sup> David Kessler and other members of the Koop-Kessler advisory group to discuss their efforts ~~to develop an expanded blueprint on tobacco control.~~ <sup>are</sup>

<sup>During</sup> 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. <sup>During</sup> 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 ~~Bruce let's talk about this -- there are downsides.~~ <sup>if we need one.</sup> (We prefer to leave this question open right now.)  
Schedule

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

|                                                                        |                                                                                                            |
|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Week of June 23:<br><del>analytic tasks.</del>                         | <del>Work groups convened, subgroups assigned</del>                                                        |
| June 27:<br><del>process.</del>                                        | <del>Donna and Bruce brief press on process and conduct first outreach meeting and press briefing on</del> |
| Week of June 30:<br><del>key remaining issues.</del>                   | <del>Groups/ Subgroups provide preliminary assessments/ define of</del>                                    |
| Week of July 7:<br><del>and synthesize work</del>                      | <del>Groups/ Subgroups develop options for outstanding issues</del>                                        |
| <del>Continue White House meetings with public health groups and</del> |                                                                                                            |
| <del>Begin meetings with members of Congress.</del>                    |                                                                                                            |
| 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:  
to ~~firm-up~~ options.

~~discuss~~

Week of July 21:  
late July/early Aug:

Possible public hearing with ~~VP~~ the Vice Pres.

Initial meeting with the President

Presidential decision ~~and announcement~~

Eliz -

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

Good job.

Eliz

# PRESIDENT CLINTON OUTLINES TOBACCO SETTLEMENT REVIEW PROCESS

Today, during the signing of the Safe and Drug-Free Communities Act, President Clinton <sup>reiterated his commitment to a</sup> ~~provided details of the~~ process the Administration will use to conduct its rigorous <sup>public health</sup> review of the Attorneys General's proposed settlement with the tobacco industry. The President also announced that Secretary of Health and Human Services Donna E. Shalala and Assistant to the President for Policy Development and Director of the Domestic Policy Council Bruce Reed will lead the comprehensive analysis. <sup>Domestic Policy Advisor</sup>

<sup>Public Health</sup>

## Preliminary Review Process

As President Clinton said today, the Administration's preliminary analysis will be conducted by four interdepartmental review panels. Each panel will include representatives from the Domestic Policy Council (DPC) and the Department of Health and Human Services (HHS), and all of them will also include representatives of other federal departments, such as the Departments of Treasury, Justice, and Labor, as subject matter suggests. ~~In detailing this review process, the President noted that this framework might change as the Administration moves from analyzing individual issues to evaluating the proposed settlement as a whole.~~ The four preliminary 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. ~~In addition to HHS and the DPC, the Department of Labor and the Environmental Protection Agency will be represented on this panel.~~
- **Program and Budget Issues.** The program and budget panel will look 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 examine ~~the interaction between the funding for children's health insurance contained in the budget reconciliation legislation and the additional funding proposed in the settlement.~~ <sup>and other public health programs.</sup>
- **Legal Issues.** The legal panel will examine 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 different units within the Department of Justice.~~
- **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. ~~In addition to representatives of the DPC and HHS, the Department of the Treasury and the Council of Economic Advisors will be represented on this panel.~~ <sup>This panel will include with</sup>

## President Clinton's Plan to Reduce Youth Tobacco Use

On August 23, 1997, 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. ~~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.~~

## **Question and Answer on Tobacco Settlement Proposal Review Process**

June 27, 1997 -- draft --

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

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

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

(more detailed descriptions of groups below)

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

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

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

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

settlement, but he is delighted that the actions of his administration and the steadfast efforts of the attorneys general have permanently changed the tobacco landscape.

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

*sure*

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

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

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

**Q. Who will lead the HHS team?**

**A.** Secretary Shalala and Deputy Secretary Kevin Thurm.

**Q. Who will lead the DPC team?**

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

**Q. Have any of the panels met?**

**A.** All of them have met at least once.

**Q. Why is this taking so long?**

**A.** This is a critical public health issue and the agreement is complex, so we are going to do an expeditious but careful and thorough review. As the President has said, protecting the public health -- and particularly our children's health -- is our primary concern. We know that nearly 3,000

young people become regular smokers each day, and nearly 1,000 of these children and adolescents will die early from their use of tobacco products. We must ensure the agreement is in the best interest of public health and children's health.

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

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

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

A. TBD

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

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

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

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

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

*This leads each*

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.

*mass. set*

June 27, 1997

NOTE TO:    Erskine Bowles  
              John Podesta  
              Sylvia Matthews  
              Rahm Emanuel  
              Mike McCurry  
              John Hilley  
              Maria Echaveste  
              Bruce Lindsey

Attached is a slightly revised version of yesterday's memo to the Chief of Staff regarding the tobacco settlement review. We've modified the schedule on the third page somewhat.

*Next time to: Sperling / Tarullo*

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

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

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

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

(more detailed descriptions of groups below)

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

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

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

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

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

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

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

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

**Q. Who will lead the HHS team?**

A. Secretary Shalala and Deputy Secretary Kevin Thurm.

**Q. Who will lead the DPC team?**

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

**Q. Have any of the panels met?**

A. All of them have met at least once.

**Q. Why will this take so long?**

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

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

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

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

**A.** TBD

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

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

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

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

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

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ADMINISTRATION

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## PRESIDENT CLINTON OUTLINES TOBACCO SETTLEMENT REVIEW PROCESS

Today, during the signing of the Safe and Drug-Free Communities Act, President Clinton <sup>public health</sup> ~~provided details of the~~ <sup>reiterated his commitment to</sup> ~~process the Administration will use to conduct its rigorous review of the proposed settlement.~~ The President also announced that Secretary of Health and Human Services Donna E. Shalala and ~~Assistant to the President for Policy Development and Director of the Domestic Policy Council~~ <sup>Domestic Policy Advisor</sup> Bruce Reed will lead the comprehensive analysis.

Public Health Review  
Preliminary Review Process

As President Clinton said today, the Administration's preliminary analysis will be conducted by four interdepartmental review panels. Each panel will include representatives from the Domestic Policy Council (DPC) and the Department of Health and Human Services (HHS), and all of them will also include representatives of other federal departments, such as the Departments of Treasury, Justice, Labor, Agriculture, Veterans' Affairs, Interior, and Defense, as subject matter suggests. ~~In detailing this review process, the President noted that this framework might evolve as the Administration moves from analyzing individual issues to evaluating the proposed settlement as a whole.~~ The four ~~preliminary~~ 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. ~~In addition to HHS and the DPC, the Departments of Justice, Labor and Treasury, the General Services Administration, and the Environmental Protection Agency will be represented on this panel.~~
- **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. ~~In addition to HHS and DPC representatives, the panel will include staff from the Department of the Treasury and the Environmental Protection Agency.~~ <sup>and other public health and</sup> ~~The panel will also examine the funding for~~
- **Legal Issues.** The legal panel will examine issues around liability, enforcement, compliance, and the disposition of tobacco industry documents. ~~In addition to DPC and HHS staff, this panel will include representatives from a number of different units within the Department of Justice, as well as staff from the Departments of Treasury and Interior.~~ <sup>research</sup>
- **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. ~~In addition to representatives of the DPC and HHS, the Department of the Treasury and the Council of Economic Advisors will be represented on this panel.~~ <sup>Programs</sup>

### 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.

Bruce  
Elena